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Evaluation of Vasectomy Success in Nepal

A Statistical Report

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A Statistical Report on the Evaluation of Vasectomy Success in Nepal

Overview

This report presents:

- a summary of the analytical and data management procedures and
- highlights of results of the evaluation of vasectomy success in Nepal.

Study Objectives

The main study objective was to:

- estimate prevalence of vasectomy failure at least 6 months after first vasectomy in a sample of men who had the procedures from 1996 to 1999 in Nepal. The key outcome of interest is persistent sperm, as defined below.

The secondary objectives were to:

- assess the extent of association between vasectomy failure, defined in alternative ways, and selected characteristics of study participants (age, age of wife), site characteristics (e.g. vasectomy performed in camps or other sites) and characteristics of surgical techniques that sample surgeons reportedly performed (fascial interposition, excision of over 2 centimeters (cm) vas), surgeon experience (number of vasectomies ever performed midway through the study period), and year/season vasectomy was performed.

- assess the sensitivity and specificity of the VasMarq test, a semi-quantitative on-site test for sperm in semen relative to sperm concentration determined by laboratory semen analysis.

Study Design

The target population was initially defined to be all first vasectomies performed in the previous two years prior to data collection in the Hill Districts of Nepal. A sample of these vasectomies was selected using two-stage stratified sampling procedure. The strata consist of four development regions, namely: Western, Eastern, Far-West, and Central regions. At stage one, one district from each of these regions was randomly selected. A list frame of all vasectomies performed in all service delivery points in sample districts in the previous two years was prepared. At stage two, a simple random sample of vasectomies was obtained from the list frames.

The initial stage-two sample of vasectomies, however, was replaced. With pilot results showing lower location rates and response rates than planned, it was necessary to obtain a sample of vasectomies larger than initially considered. Moreover, with considerable delay in start of data collection, almost a year passed so that the list frame of vasectomies was expanded to include vasectomies in the previous year. This change led to a new target population: first vasectomies performed in the last **three** years prior to data collection. The stage-one sample districts remained the same because the proportionate increase in number of vasectomies was more or less the same across regions. The second stage list frame was expanded to include vasectomies in the last year prior to data collection and a sample of vasectomies from each district was redrawn from the expanded list frames.

The stage-two sample of vasectomies was randomly divided into main and hold-out samples. Main samples were immediately fielded for location and interview. The decision as to whether the hold-out

sample would be fielded depended on the location and response rates midway through data collection. As it turned out, no hold-out vasectomy samples were fielded.

For logistical reasons, only men residing in catchment areas of sample service delivery points were included in the study. Estimates of proportion of out-of-area vasectomies were obtained from the list frames. Moreover, estimates of first vasectomies were obtained during interviews. Adjustment of total vasectomies by region was based on estimates of out-of-area obtained from the list frame and first vasectomy proportions obtained from interviews.

Definition of Outcome Variables

Various measures of vasectomy failure were defined as follows:

Overt Failure – a dichotomous variable which equals '1' if the sperm concentration is greater than or equal to 2 mil/ml, and equals '0' otherwise. Should correspond to a subject's final outcome status.

Indeterminate – a dichotomous variable which equals '1' if the sperm concentration is greater than or equal to 0.5 mil/ml but less than 2.0 mil/ml, and equals '0' otherwise. Should correspond to a subject's final outcome status.

Presumed Success – a dichotomous variable which equals '1' if the sperm concentration is less than 0.5 mil/ml, and equals '0' otherwise. Should correspond to a subject's final outcome status.

Persistent Sperm - a dichotomous variable which equals 1 if overt failure or indeterminate outcome is detected, and equals '0' otherwise This is the main outcome of interest.

Reported pregnancy – a dichotomous variable that equals '1' if a man reports a pregnancy in a sexual partner after vasectomy, and equals '0' otherwise.

Type of pregnancy outcome was defined as: 1) pregnancy conceived within three months of vasectomy or 2) pregnancy conceived three or more months after vasectomy. Pregnancies conceived within three months of vasectomies could be due to insufficient use of back-up contraception while pregnancies conceived later could be attributed to vasectomy failure.

Type of pregnancy outcome, including whether conception dates of pregnancy were available was cross-tabulated by vasectomy outcome based on sperm concentration. The numbers of days to conception of pregnancy relative to dates of vasectomy were manually calculated from reports of estimated dates of fertilization for first pregnancy following vasectomy, and dates of vasectomy. Such dates were reported as Nepali dates. The date of fertilization for any pregnancy was estimated during the client interview and/or during a follow-up visit.

VasMarq outcome - is a dichotomous variable that takes the value of '1' for a positive test result and 0 for indeterminate or negative test result.

Covariates based on interviews of surgeons and interviews of sample men were constructed. Definitions of these covariates are in Appendix I.

Study Analysis Populations

We defined four analysis populations, namely:

1) interview analysis population
2) primary analysis population
3) excluded population
4) laboratory analysis population.

The criteria used in defining the above analysis populations were:

1) interview was done
2) vasectomy was first or repeat as indicated by men during interview
3) semen specimen was provided, and laboratory sperm concentration was valid.

The interview analysis population consisted of men who were located and interviewed with respect to their first vasectomies. As indicated during interview, ten men had repeat vasectomies: two had sample vasectomy dates that referred to their first vasectomies and eight had dates that referred to second vasectomies. Two of the repeat vasectomies with interviews referring to the first vasectomy were included in the interview population but not in the primary analysis population. Eight of the repeat vasectomies were excluded from the interview analysis population as their dates of vasectomies referred to the second rather than the first ones.

The primary analysis population consisted of men with first vasectomies and valid laboratory results (sperm concentration) for semen specimen.

The excluded population consisted of :

1) men who were located and interviewed with respect to their second vasectomies or
2) men who were interviewed with respect to their first vasectomies but did not provide semen sample.

The laboratory analysis population consisted of men with both valid laboratory tests (sperm concentration) and VasMarq test result regardless of whether vasectomy was first or repeat.

The various types of analyses for which the above analysis populations were used are in Table 1. These types of analyses included:

1) descriptive statistics (unweighted counts, unweighted percents and weighted percents, mean, standard errors and range, depending on whether characteristics were reported as categorical or continuous variables)
2) analysis of vasectomy outcome based on sperm concentration in semen
3) analysis of vasectomy outcome based on pregnancy reports
4) assessment of sensitivity and specificity of VasMarq results in assessing vasectomy outcome based on sperm concentration. Sperm concentration was considered gold standard.
5) association of vasectomy outcome with selected site, surgeon, couple characteristics, year vasectomy was performed, in bivariable or multivariable modelling.

Table 1. Summary of Types of Analyses for Various Analyses Populations

	Analyses Populations			
Types of Analyses	Primary Analysis Population (n=924)	Interview Analysis Population (n=1052)	Excluded Population (n=128)	Laboratory Analysis Population (n=930)
1) Descriptive Statistics for Demographic/Contraceptive/ Site/Surgeon Characteristics	X	X	X	
2) Vasectomy Outcome based on Sperm Concentration	X			
3) Vasectomy Outcome Based on Pregnancy Reports	X	X		
4) Sensitivity/Specificity of VasMarq Results Relative to Sperm Concentration				X
5) Association of Selected Characteristics with Vasectomy Outcome	X			

Depending on the type of analysis, a certain subset of the primary analysis population was excluded from the analysis. Details of exclusions are presented below.

Analyses Weights and Variance Strata

We constructed separate analysis weights for the interview, primary and laboratory analyses populations. The analysis weights for the interview analysis population were constructed so that the sample represented all first vasectomies reported in 1997 to 1999 with adjustments for not locating some of the study participants. The analysis weights for the primary analysis population were those of the interview population adjusted for loss of valid semen specimen. The analysis weights for the laboratory analysis population were constructed to represent all vasectomies (first and second) reported in 1996 to 1999 vasectomy seasons in all hill districts of Nepal.

For each analysis population, unadjusted unconditional probabilities of selecting a vasectomy within a region and adjustment factors were calculated. The unadjusted unconditional probability of selecting a vasectomy in a region was the product of :

1. probability of selecting a district, which is equal to one divided by the total number of districts within a region.

2. probability of selecting vasectomy from a sample district. This is equal to the total number of men selected divided by the total number of vasectomies within the districts.

Two adjustments were made to the unadjusted unconditional probability of selecting a vasectomy. The first adjustment was done so that the resulting probabilities would reflect the 'true' proportion of regional total vasectomies to the total vasectomies in the study population. That is, an adjustment was made so that the total weighted counts in the region represented the total number of vasectomies in that region. To do this, we obtained the ratio of :

1) the probability of selecting sample vasectomies in a region as if a simple random sample of vasectomies were selected from the regional totals to
2) the unadjusted unconditional probability of selecting vasectomies computed based on the two-stage sampling above.

The simple random sample probabilityof sampling was further adjusted to reflect the estimated number of *first* vasectomies in the region. Such adjustment was done for the primary and interview analysis population. For the laboratory analysis population, no adjustment for first vasectomy was done.

The second adjustment was done to account for nonresponse within region. The unadjusted unconditional probability of vasectomy in a region was multiplied by the response rate in the same region.

Overall, the adjusted unconditional probability of selecting a vasectomy was a product of the unadjusted unconditional probability, ratio factor and nonresponse rate. The inverse of this adjusted probability of selecting a vasectomy was the analysis weight. The spreadsheet for calculating analysis weights is in Appendix II. In this spreadsheet are total counts of vasectomies by region, adjustments for location, interview completion, availability of valid semen specimen as well as resulting analysis weights for the various analysis populations.

With men clustered within regions and surgeons, variance estimates were calculated where men within surgeons formed clusters. Regions (essentially districts) comprised the sampling strata. The variance strata based on surgeon in each district were coded as follows:

- Site/Region/District 1: cluster 1=surgeons 11, 14, and 15; cluster 2=surgeon 12; cluster 3=surgeon 13; cluster 4=surgeon 16; and cluster 5=surgeon 17.
- Site/Region/District 2: cluster 1=surgeons 21and 24; cluster 2=surgeon 22; cluster 3=surgeon 23.
- Site/Region/District 3: cluster 1=surgeons 31 and 34; cluster 2=surgeon 32; cluster 3=surgeon 33.
- Site/Region/District 4: cluster 1=surgeries performed by surgeon 41 in 2053; cluster 2= surgeries performed by surgeon 41 in 2054; cluster 3= surgeries performed by surgeon 41 in 2055.

Data Management Issues

The data management procedures for this project were relatively complex due to various study design features:

1. Data were collected using various questionnaires administered to or completed by :

   1.1. men (e.g. interview questionnaires)
   1.2. surgeons
   1.3. laboratory technicians

   For men with initial persistent sperm after vasectomy (as reported in the Nepal F2 laboratory), FSI laboratory staff confirmed sperm concentration and subject specialists decided which of the alternative laboratory results to use in the analysis. Quality control and validation of semen specimen were completed at various time points and validated laboratory data were differentiated from initial laboratory data.

2. Dates were reported in Nepali instead of Julian dates, thereby complicating calculations of date variables (the Nepali Vikram Sambat calendar months have 28-32 days). Several dates were manually calculated independently by two staff and later combined with other datasets.

3. data entry and data checking were accomplished using a new approach, utilizing Web-based software for electronic data capture.

Two statistical programmers independently prepared the dataset used in the analysis for this report. Further corrections were noted as statistical tables were generated.

Statistical Methods

Unweighted and Weighted Statistics

We reported unweighted counts, unweighted percents and weighted percents in most of the analyses. Because the sample was selected using complex sampling procedures (stratified, with unequal probability of selection across strata, and clustered within districts and surgeons), we used either SAS or SUDAAN procedures specific to complex sample survey data. In these procedures, we specified site, clusters of surgeon and adjusted sampling weights to account for the complex sampling procedures.

We presented descriptive statistics for the interview, primary and excluded analysis populations. Because the proportion of the excluded analysis population was less than 15% of the fielded sample, we did not conduct statistical test of the significance of differences in characteristics of primary and excluded analysis populations.

Variance and Confidence Intervals for Vasectomy Failure Using Dichotomous Outcomes

Estimates of prevalence of vasectomy failure based on sperm concentration were produced using SAS survey procedures.

Association of Dichotomous Vasectomy Failure with Selected Covariates

Four dichotomous vasectomy failure measures were associated with selected covariates, namely:

1) overt failure (e.g. having at least 2 million sperm/ml is 1 and zero otherwise)
2) persistent sperm (e.g. having at least 0.5 million sperm /ml is 1 and zero otherwise)
3) any type of failure based on persistent sperm or any pregnancy report (e.g. either persistent sperm or any pregnancy report)
4) any type of failure based on persistent sperm or pregnancy that occurred at least three months after vasectomy.

Estimates of association of dichotomous vasectomy failure with selected covariates were estimated using SUDAAN logistic procedure. These covariates were: 1) site of vasectomy was either camp or

others; 2) surgeon used fascial interposition or not; 3) surgeon excised greater than 2 cm of vas or not; 3) surgeon's experience below or above median (based on number of vasectomies ever performed by surgeons half-way throughout the period covered by study); 4) men's age in interval of 18-25, 26-30, 31-35 and over 35; and subsequently continuous age expressed in 5-year age intervals; 5) wife's age in intervals of 18-27,28-33 and over 33 and continuous age expressed in 5-year intervals; and 6) year/season vasectomy was performed-1996/1997 season; 1997/1998 season and 1998/1999season. In fitting multivariable logistic models, age of either men or wives was entered as continuous variables with 5-year interval per unit.

To assess whether all of the above characteristics, except year vasectomy was performed, may be kept in a multivariable model, a full model using SAS logistic procedure with backward elimination was used. Furthermore, the correlation of the above covariates with each other and with alternative measure of vasectomy outcome was assessed for high correlation that may lead to covariates aliasing effects with other covariates. Year of vasectomy was used only in bivariable modeling.

A final multivariable model was fitted for two outcome variables: 1) persistent sperm and 2) pregnancies three or more months after vasectomy, with pregnancies in the first three months coded as 0. For the multivariable logistic model of persistent sperm, the covariates included whether surgeons performing vasectomies had routinely used fascial interposition, excised greater than 2 cm vas, special technique used by surgeon 41 (ends of the vas folded back, as well as greater than 2 cm excision), number of vasectomies completed in 100 vasectomies per unit, and age of study participants in 5-year interval. For the multivariable logistic model of pregnancy, all surgeon experience variables used in the persistent sperm model were included plus age of wife of study participants in 5-year interval.

Twelve men in the primary analysis population were excluded in fitting the multivariable model for persistent sperm because the number of vasectomies completed by surgeon for these men was missing. Furthermore, seven more men were excluded from the pregnancy model as these men did not report age of their wives.

Estimation of Vasectomy Failure Prevalence from Pregnancy Reports

Pregnancy statistics were calculated in two ways:

1) Kaplan-Meier (KM) procedures in SAS Lifetest where clustering and weighting were ignored and
2) piece-wise exponential modeling at 3, 6, 12, 24, and 36-month intervals where clustering of men's wives and weighting were considered.

SAS genmod procedure was used to estimate log of hazard estimates at each interval. An approximation of the Poisson-distributed hazard was obtained by fitting a logistic model of pregnancy where the number of months of exposure was multiplied by 10000. Coefficients for predicting log of hazard estimates were read into SAS proc IML to obtain an estimate of probability of success (e.g. not getting pregnant), standard error and 95% confidence interval for probability of success. Estimates of failure (e.g. probabilities of getting pregnant) were calculated as one minus the estimate of cumulative probability of success. The 95% confidence intervals for probabilities of pregnancy (e.g. probabilities of vasectomy failure) were based on one minus the lower or upper limit for probabilities of success (e.g. not getting pregnant). Estimates of standard errors were based on first-order Taylor series

approximation. Two options for clustering were used in estimating predictors for log of hazard: 1) clustering of pregnancy intervals within women (e.g. women contributed to various pregnancy intervals depending on estimated date of pregnancy; for example, a woman whose pregnancy was estimated to be beyond 25 months contributed to five intervals while a woman whose pregnancy was within the first three months of vasectomy contributed person time to the first pregnancy interval) and 2) clustering of sample men (and indirectly of women) within surgeons. Because results were identical for most intervals, only results from a model based on clustering of pregnancy intervals within women are reported in the main body of results.

Estimates using KM were or more or less the same with estimates obtained using piecewise exponential modeling of hazard except at the last interval. KM estimates of cumulative probability of not getting pregnant was higher than that of the piece-wise exponential fitting. Only estimates based on the piece-wise life table analyses are presented in the main body of tables.

We used various subsets of the primary analysis and interview analysis populations to analyze pregnancy reports. These subsets were based on:

1) whether days of conception relative to vasectomy dates were available,
2) pregnancy occurred within 3 months of vasectomy.

We imputed days to conception relative to vasectomy for three wives known to have been pregnant but with no approximate dates of conception. We grouped the estimated dates of fertilization into five intervals: 0-3, 4-6, 7-12, 13-24, 25-36 and estimated cumulative percent distribution of women with reported pregnancies. This estimated cumulative percent distribution was as follows:

Interval	Cumulative Percent
0-3	23
4-6	40
7-12	54
13-24	83
25-36	100

We generated uniform random numbers for each woman with no pregnancy dates and assessed in which of the five intervals these random numbers fell. The woman randomly assigned a uniform random number equal to .33 was assigned to time interval 4 to 6, because .33 was between .24-.40, the cumulative percent for interval 4-6. Similarly, women randomly assigned uniform random numbers of .71 and .92 were assigned to time intervals 13-24 and 25-36, respectively. We assigned the midpoint of the time interval as the woman's days of conception relative to vasectomy. We assessed the effects of such imputation on estimates of cumulative probability of reporting pregnancy by including and excluding such women from KM or piecewise-exponential estimation.

We estimated KM and piece-wise exponential models of cumulative probability of pregnancies on five subsets of the primary analysis population, namely:

1) all study participants in the primary analysis population with all pregnancies considered valid events regardless of pregnancy timing relative to vasectomy and using imputed values for three women (n=924)

2) all study participants in the primary analysis population with pregnancies after three months were considered valid events including three with imputed values (n=924). Early pregnancies were censored in this subset (n=924). This assumes that early pregnancy was not due to vasectomy procedure.
3) all study participants in the primary analysis population excluding pregnancies with missing dates of days of conception relative to vasectomy (n=921). Early pregnancies were censored in this subset.
4) all study participants in the primary analysis population excluding pregnancies with early or missing dates of days of conception relative to vasectomy (n=914).
5) all study participants in the primary analysis population excluding women with early pregnancies (n=917).

Results from piece-wise exponential fitting for subsets one and four are presented in the main body of statistical results. These are the subgroups in which difference in estimates of cumulative probability of failure may be qualitatively considered a bit substantial. In Appendix III are estimates of cumulative percent of vasectomy failure and their standard errors by time intervals for all of the five subgroups defined above as estimated using KM and piecewise exponential model fitting.

Sensitivity/Specificity Analyses

We initially estimated the sensitivity, specificity, positive predictive value and negative predictive value of Vasmarq results relative to vasectomy outcome based on two cut-off points for sperm concentration. One cut-off was at least 2 million sperm/ml (e.g. overt failure) and the other was at least 0.5 million sperm/ml (e.g. persistent sperm). We calculated unweighted and weighted estimates of the above four statistics using SAS proc freq and data steps. To validate the estimated statistics from SAS, we ran STATA logistic procedure and used its option to calculate predicted values and the above four statistics.

Subsequently, we estimated the unweighted sensitivity at two additional cut-points, 5 million sperm/ml and 10 million sperm/ml, using SAS proc freq and data steps.

Statistical Tables and Selected Results

The statistical tables for this study are grouped into four:

1) Series A tables describe the study population and sample by analysis populations
2) Series B tables present vasectomy outcome statistics for the primary analysis population
3) Series C tables present pregnancy statistics for the interview analysis population and
4) Series D tables present results of the sensitivity/specificity analysis.

All tables are in Appendix IV. Selected highlights are presented in this section.

Series A: Study Population, Sample and Selected Characteristics of Analysis Populations

Study Population and Sample

In Table A.1 are unweighted counts of the total vasectomy population in Nepal hill districts from 1996 to 1999, projected counts of vasectomy among men residing within catchment areas, projected counts of first vasectomies, and total number of districts from which the sample men/vasectomies were obtained, by Nepal's development region.

From a total of 32 districts, four districts, with one district randomly selected from each of the four regions, comprised the first stage sample. Estimated number of vasectomies from these sample districts was 3040 of which 1500 were taken as second stage sample. From the sample of 1500, a total of 1263 vasectomies were fielded for interviews.

In Table A.2 is the fielded samples' study disposition status by district. In Figure 1 is the fielded samples' study disposition status across districts.

Of the 1263 fielded sample, 1060 were successfully located and interviewed for an overall location rate of about 84%. Bhojpur had the lowest location rate at 76% and Ramechap had the highest location rate at about 88%. Ten of the completed interviews were among men who had repeat vasectomies and the rest (1050) were among men who had their first vasectomies.

Of the interviewed men, 980 (971 among first vasectomies and 9 among repeat vasectomies) provided semen specimen. Of the first vasectomies providing semen, 924 had a valid semen specimen. This group comprised the primary analysis population.

Of the interviewed men, 1052 comprised the interview analysis population. Included in this study domain were two repeat vasectomies whose semen sample was excluded from the primary analysis population. Eight of the ten repeat vasectomies were excluded from the primary analysis population as their responses to interviews referred to their second rather than first vasectomies. The excluded population consisted of 128 men who had completed interviews but had no semen specimen and eight of the ten repeat vasectomies.

Of those who provided semen, 930 were included in the laboratory analysis population. Three were excluded for lack of VasMarq reading and 47 were excluded for no valid sperm concentration.

Characteristics of Analysis Populations

In Table A.3.1, A.3.2, and A.3.4 are selected demographic characteristics, types of counseling provided, and surgeon characteristics, respectively, by analysis populations. In Table A.3.3 are unweighted counts and weighted percents of counseling provided by year of vasectomy for the primary analysis population.

Over 99% of the sample was married at the time of vasectomy; average age was 32 years for the interview and primary analysis populations, and 34 years for the excluded population. The average age of wives was 28 for both the interview and primary analysis populations and 29 for the excluded population. The average number of sons was larger than the average number of daughters in all of the analysis populations: 2 and 1.6, respectively, in the primary and interview analysis populations and 2.4 and 1.7, respectively in the excluded population.

Most men reported being told to use condoms (92% in primary and interview analysis populations and 87% in excluded populations). Over 80% of the analysis populations reported ever using a condom, predominantly as a back-up to prevent pregnancy. Only about 2% reported condom use as a method to prevent disease. Over 85% were provided condoms after vasectomy and over 50% reported this method as contraceptive method during three months after vasectomy, compared with 13% using this method during three months before vasectomy.

Regardless of year of vasectomy, over a quarter (e.g. weighted percent) of the primary and interview analysis populations did not remember for how long they had to use back-up contraceptive methods and

40% of the excluded population did not remember. Almost half of the participants recalled being told that vasectomy was 100% effective (completely reliable).

In the primary and interview analysis populations, vasectomy was completed mostly in camps (over 93% of the primary and interview populations and 86% of the excluded population). Surgeons who reported routinely using fascial interposition performed vasectomies on almost 9% of men in the primary analysis population. Surgeons who routinely excised greater than 2 cm of vas performed over 60% of vasectomies in the primary analysis population. Notably, a single surgeon who accounted for almost 50%` of sample vasectomies, routinely used a special technique whereby >2cm was excised and both ends of the vas were folded back (data not shown).

Overall, the excluded population exhibited some characteristics that differ from those of the primary analysis population. No statistical test of such difference was done.

Series B Prevalence of Vasectomy Failure in the Primary Analysis Populations

In Table B.1 are unweighted counts, unweighted percents and weighted percents of prevalence of vasectomy failure using various measures. The prevalence of persistent sperm was 2.3 % with 95% confidence interval (CI) of 1.1 % to 3.6%. Persistent sperm was found among 23 men in the primary analysis population. Of the 23 men with persistent sperm, 18 were overt failures (>= 2 million sperm/ml). The prevalence of overt failure was 1.8% (0.8%-2.9% 95% CI). A listing of the sperm concentrations of men with non-zero sperm concentration or sperm viability is in Appendix V.

Thirty-two men reported pregnancy among their wives for pregnancy prevalence of 3.3% (1.8%-4.8% 95% CI). Of these pregnancies, seven occurred within three months of vasectomy, 22 occurred three or more months after vasectomy and three occurred with no known dates relative to vasectomy.

The concordance of vasectomy failure based on laboratory measures of sperm concentration and vasectomy failure based on reported pregnancy was moderate: kappa statistics was 0.53 including all pregnancies and 0.48 including pregnancies three or more months after vasectomy (Table B.2). Of 23 men with persistent sperm, 15 reported pregnancies and 8 did not report any pregnancy. Of the 22 pregnancies conceived three or more months after vasectomy, 11 were among men with persistent sperm and the other 11 were among men with presumed vasectomy success.
In Figure 2, sperm concentration for each of 23 men with persistent sperm count is shown by months since vasectomy. (Sperm concentration is on a logarithmic scale.) More than half of men with persistent sperm count were oligozoospermic (13 out of 23 men had sperm count below 10 million sperm per ml). Of eight pregnancies that occurred among those with persistent sperm, three occurred among men whose sperm count was 'indeterminate' (e.g. 0.5 to 2 million sperm/ml). The number of cases of persistent sperm appears to increase with years since vasectomy procedure. There were four, eight and 11 men with persistent sperm counts in year one, two and three years after vasectomy, respectively.

Figure 3 presents the proportion of men having persistent sperm by year after vasectomy. Our assumption (Philip T, Guillebaud J, Budd D. Complications of Vasectomy: Review of 16,000 patients. Br J Urol 1984; 56(6): 745-8.) was that recanalizations would be apparent within the 6-12 months after vasectomy, and thus persistent sperm would be the same regardless of which year the vasectomy was performed. However, as shown in Figure 2, the proportion appears to increase with years after vasectomy. These are weighted estimates for each year/season (n=312, 364, 248).

In Table B.3 are the cumulative percents of pregnancy among 100 women at 3, 6, 12, 24 and 36 months after vasectomy by timing of pregnancy: e.g. any pregnancy regardless of timing and pregnancy three or more months after vasectomy. The 12-month rate for all pregnancies was 1.8% (1.4%-2.3% 95% CI)

and for pregnancy three or more months after vasectomy, the 12-month rate was 1.1% (0.6%-1.5% 95% CI).

Figure 4 shows the cumulative probabilities of all pregnancies and cumulative probabilities of pregnancies presumed conceived 3 months or more after vasectomy. Excluding pregnancies occurring within 3 months, the cumulative probability of pregnancy increased proportionally with time (the risk of pregnancy appears to be constant during the period 6 months to 3 years after vasectomy).

Series B Correlates of Persistent Sperm and Pregnancy 3 or More Months After Vasectomy

In Table B.4 are unweighted counts and unweighted and weighted proportions of vasectomy outcomes by selected site, surgeon and study participant characteristics for the primary analysis population. In Table B.5 are odds ratios and 95% confidence intervals for these odds ratios estimated from logistic regressions for various measures of vasectomy outcome and a single predictor variable.

Results are reported for four measures of vasectomy outcome: 1) overt failure; 2) persistent sperm; 3) any failure based on persistent sperm or any pregnancy and 4) any failure based on persistent sperm or pregnancy three or more months after vasectomy. In this latter outcome, pregnancy within three months of vasectomy was considered to be a non-event. That is, men reporting such pregnancy were included in the analysis but pregnancy was coded as zero.

For any of the four outcomes considered, rates of vasectomy failure were higher among those with vasectomies performed in locations other than in camps (Table B.4). This association of vasectomy failure with type of site, however, was not statistically significant (Table B.5) at 5 percent significance level. The estimated odds ratio was 0.4 with 0.1-1.1 95% CI; with an odds ratio of one contained within the 95% CI, the association between overt failure and type of site was not statistically significant.

Failure rate was higher among those whose vasectomy was performed by surgeons who reported routine use of fascial interposition (FI) than among those whose vasectomy was performed by surgeons not using this modified technique. Such bivariable association was statistically significant with odds ratio of 4.6 (2.3-9.2 95% CI).

Failure rate was lower among those whose vasectomy was performed by surgeons who routinely excised greater than 2 cm vas than those whose vasectomy was performed by surgeons not using this modified technique (Table B.4). This association, however, was not statistically significant except when outcome was persistent sperm (Table B.5).

Failure rate was highest among men whose vasectomies were performed by surgeons with the most number of completed vasectomies. This association was not statistically significant. The older the wife was, the less likely that vasectomy failure was reported. The youngest men (18-25) had the highest failure rate by age groups. This bivariable association of men's age or wife's age with vasectomy failure was not statistically significant.

In Table B.6 are results of multivariable logistic regression for two outcomes: 1) persistent sperm and 2) pregnancies three or more months after vasectomy. In these multivariable logistic regressions, several

predictors were included, namely: surgeon's routine use of fascial interposition, routine excision of greater than 2 cm vas, average number of vasectomies in units of 100 vasectomies performed by surgeon midway through the study period, special technique attributable to surgeon 41, and age. For persistent sperm, age of study participant was an added predictor and for pregnancies three or more months after vasectomy, age of wives was an added predictor.

In a multivariable logistic regression model for persistent sperm, all covariates except surgeon's who routinely excised greater than 2 centimeters of vas, had no statistically significant association with persistent sperm. Men whose vasectomies were performed by surgeons who routinely excised greater than 2 centimeters were one-third less likely to have persistent sperm than men whose vasectomies were performed by surgeons not using this modified technique, while holding other covariates constant.

In a multivariable logistic regression model for pregnancies three or more months after vasectomy, greater than 2-centimeter excision and age of wives were statistically associated with failure. As in the persistent sperm model, men whose vasectomies were performed by surgeons who routinely excised greater than 2-centimeter of vas were one -third less likely to report any failure than men whose vasectomies were performed by surgeons who did not, while holding other covariates constant. Men whose wives were older were half as likely to report any failure, while holding other covariates constant. The odds of pregnancy is less likely with elder wife, OR=0.5, 95%CI=0.3,0.9.

Figure 5 illustrates the proportion of reported pregnancies by wife's age at time of vasectomy. The proportions were highest for the youngest women, and no pregnancies were reported in women over the age of 33.

It is important to note that surgeons' techniques and level of experience were reported by the surgeons directly. Such techniques and level of experience did not necessarily apply to each man in the sample. Moreover, surgeons in this study were not necessarily a representative sample of surgeons performing vasectomy in Nepal. With these constraints, results of multivariable models relating surgeon techniques and experience with vasectomy outcome must be interpreted with caution.

The results of prevalence of vasectomy failure, however, may be taken to represent prevalence in the given time period of all first vasectomies in Nepal.

Series C Pregnancy Statistics Among Interview Analysis Population

In Tables C.1 and C.2 are prevalence rates for pregnancy and cumulative probability of pregnancy in the interview analysis population. Prevalence of all pregnancies was 3.3 % (1.8%-4.8% 95% CI). Cumulative probability for all pregnancies at 12 months after vasectomy was 1.7 % (1.4%-2.1% 95% CI). At 36 months after vasectomy, the cumulative probability for all pregnancies was 4.2% (3.2% - 5.2% 95% CI). Based on pregnancies 3 or more months after vasectomy, the cumulative probability of pregnancy at 12 months after vasectomy was 1.0% (0.6%-1.4% 95% CI), and at 36 months after vasectomy, 3.2% (2.2%– 4.1% 95% CI)

Series D Sensitivity and Specificity Analysis

With sperm concentration as gold standard, the sensitivity, specificity, positive predictive values and negative predictive values of VasMarq readings were calculated. Two cut-off points for sperm concentration was used in computing the above statistics: greater than 2 million sperm/ml and greater than 0.5 million sperm/ml.

With greater than 2 million sperm/ml as 'true' cut-off designating vasectomy failure, VasMarq was 50% sensitive and 96.4% specific. Of those with positive VasMarq result, 21.4% were 'truly' positive and of those with negative VasMarq, 99% were truly negative, based on sperm concentation.

When the cut-off for true vasectomy failure was at least over 0.5 million sperm/ml, the sensitivity, specificity, positive predictive value and negative predictive value of VasMarq were 39.1%, 96.4%, 21.4%, and 98.4%, respectively.

When the cut-off for true vasectomy failure was set at 5 million sperm/ml, the sensitivity of the Vasmarq was 75%, and was 82% when the cut-off was set at 10 million sperm/ml.

Figure 6 presents a summary of the performance of VasMarq by various cut-off points, for sperm concentration.

Weighted estimates remained more or less the same as the unweighted ones.

Assessment of Design Effects

In Appendix VI are estimates of design effects for estimates of selected variables. Estimates of weighted proportions of persistent sperm, pregnancies three or months after vasectomy, and any failure in the primary analysis population had design effects of 1.4, 1.5 and 2.0, respectively.

The log of odds ratio of having persistent sperm with surgeon's who excised greater than 2 centimeters of vas was 2.2.

These design effects were within the range of design effects considered during the planning stage for this study.

Construction of Nepali Profile Dataset for Evaluation of Vasectomy Success

Combining Pharmlink Data with Information from Nepal

Data were combined from excel spreadsheets and tracking data set that initially was on a Web server.

The Pharmalink tracking dataset contained 1266 observations – two of which were the QC observations and one observation, from site 2, clieldps=9082, was a test case entered by the technical monitor. The test case and the two QC cases (site=9) were omitted, leaving 1263 observations. These 1263 observations were men selected from each district. These observations were combined, by year of vasectomy (psvasyy from the pharmalink tracking dataset and nepyear from various excel spreadsheets) and client face sheet number (fshtldps from the pharmalink tracking dataset and reg_no from the spreadsheets) with the spreadsheets above. For Doti, it was necessary to combine the data by face sheet number, year, and month of vasectomy (nep_mo as extracted from the nepdate from the spreadsheets).

Updating Nepal Sperm Concentration Data with the FSI Sperm Concentration QC Data

Fertility Solutions Inc. Cleveland, OH. (FSI) conducted the lab QC for this study. FSI had detected some systematic error in Nepal's concentration estimations at the higher sperm concentrations and also sought to validate some selected lower concentration samples. For samples validated by FSI, the FSI final concentration was substituted for the Nepal concentration. Only FSI records with a non-missing FSI concentration were used.

When available, the FSI concentration was used to determine each participant's final status. This resulted in a few reclassifications and the construction of the analysis variable OUTCOME. For all valid laboratory results (see definition below), the participant's outcome equals success if the concentration, based on the FSI concentration, if available, or on the original concentration otherwise, is less than 0.5 mil/ml; indeterminate if the concentration, is greater than or equal to 0.5 mil/ml but less than 2 mil/ml; or failure if the sperm concentration is greater than or equal to 2.0 mil/ml.

Definition of a Valid Sample

Of the 1263 men, 980 provided a semen specimen at the evaluation visit, and 283 did not. Two men provided a semen sample at a follow-up visit. The data from FSI captures this. The following rules were used to determine whether the non-FSI results obtained were valid:

1) Nolab=1 if the sample was insufficient to prepare the preserved specimen. It was insufficient if, on the accession form, Item 8, 'Was specimen analyzed?' (variable=specanal) was answered 'No';
2) Badlab=1 if the microcell results were invalid. The results were invalid if item 3 (variable=resstat) of the Microcell form was marked 'Invalid';
3) Uncertain=1 if there is reason to question the validity of the final concentration. A decision value was applied taking into account three criteria: if the specimen was low volume (<0.5 ml), the early part of the ejaculate was lost (variable=prtlosta from the semen collection form) and the dilution factor (variable=dilfact from the semen accession form) was high (>4). The specimen volume (variable=volsespe) is also on the semen collection form.
4) Three men provided a repeat semen specimen (clieldps=5087, 5089, 5156). Only the sample originally provided at the evaluation visit was used in the analysis.

5) Ten men had repeat vasectomies. For two of these men, the vasectomy that was selected in the sample was the first vasectomy. These men were included in the interview population, but their

semen results were considered invalid, thus they were not in the primary analysis population. The other eight men were neither in the interview or primary analysis populations.

Note: if a participant's sample was not valid, the participant's lab result and outcome were set to missing in the primary analysis.

Surgeon Questionnaire

For associational analysis, the surgeons were grouped based on average experience midway through the study period (number of vasectomies ever performed at end of study minus number of vasectomies ever performed at beginning of study, divided by 2) as being below the median (surgeons 12, 13, 14, 24, and 32), median (surgeon 41), and above the median (surgeons 11, 15, 16, 17, 22, 23, 31, 33, and 34). These were coded using the two dummy variables: belowmed and abovemed, with the median experience reflecting the reference group. These variables were later supplemented by the actual number of vasectomies in 100 vasectomies per unit in fitting the logistic models.

Two other variables, reflecting the surgical techniques generally used or preferred, were developed. The surgeons who used fascial interposition were surgeons 11, 23, 33, and 34. For these surgeons, the variable fi was coded '1'. Surgeons who excised greater than 2 cm of vas were 11, 12, 15, 23, 24, 33, and 41 and are coded to the variable gt2cm=1.

For the multivariable logistic model, a special technique variable to reflect technique by surgeon 41 (fold-back method) was created.

Pregnancy Analysis Variables

Two staff manually and independently computed the total days from vasectomy to pregnancy using the Nepali dates of both vasectomy and pregnancy. The date of pregnancy was obtained during the client interview and/or during a follow-up. If different, the date obtained during follow-up was taken to be the most accurate date. For the profile dataset, only the first pregnancy after vasectomy was considered.

Appendix II. Calculation of Sampling Weights for Various Analysis Populations

Region	Number of Districts	Sample Districts	# of Men in Districts	Number of Men within Districts	Total Men in Region in last 3 years	Adjusted counts of men within districts	Number of repeat vasectomies	% dist. of vasectomies	Selected Sample	Number with semen specimen	Number in primary analysis population	Number in laboratory analysis population	Number of 1st vasectomies in interview population	All Interviews
Western	10	Tanahu	1412	1232	9120	7958	4	0.259	385	286	280	285	318	322
Eastern	8	Bhojpur	456	435	3294	3143	1	0.102	152	101	94	92	115	116
Far-West	6	Doti	639	628	4444	4368	1	0.142	231	173	144	145	187	188
Central	8	Ramechap	533	495	16398	15229	2	0.496	495	420	406	408	432	434
TOTALS			3040	2790	33256	30698	8	1.000	1263	980	924	930	1052	1060

A. Primary Analysis Population

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	Prob. of Selecting District	Prob. of Selecting Men within District	Unconditional Prob. of Men/ (Vasectomies	% of Repeat Vasectomies	Adjusted Counts: 1st Vasectomies	SRS Prob. of Sample	Ratio Factor: ="(6)*)3)	Response Rate	Adj. Uncond. Prob. of men	Analysis Weights	Total Counts
Western	0.100	0.313	0.031	0.0124	7860	0.049	1.567	0.727	0.036	**28.0714**	7860
Eastern	0.125	0.349	0.044	0.0086	3116	0.049	1.117	0.618	0.030	**33.1489**	3116
Far-West	0.167	0.368	0.061	0.0053	4345	0.053	0.867	0.623	0.033	**30.1736**	4345
Central	0.125	1.000	0.125	0.0046	15159	0.033	0.261	0.820	0.027	**37.3374**	15159
Total					30480						30480

B) Interview Analysis Population

Western	0.1000	0.3125	0.0313	0.0124	7860	0.049	1.567	0.826	0.040	**24.717**	7860
Eastern	0.1250	0.3494	0.0437	0.0086	3116	0.049	1.117	0.757	0.037	**27.096**	3116
Far-West	0.1667	0.3678	0.0613	0.0053	4345	0.053	0.867	0.810	0.043	**23.235**	4345
Central	0.1250	1.0000	0.1250	0.0046	15159	0.033	0.261	0.873	0.028	**35.090**	15159
Total					30480						30480

C) Laboratory Analysis Population

Western	0.1000	0.3125	0.0313	0.0000	7958	0.048	1.548	0.7403	0.0358	**27.923**	7958
Eastern	0.1250	0.3494	0.0437	0.0000	3143	0.048	1.107	0.6053	0.0293	**34.163**	3143
Far-West	0.1667	0.3678	0.0613	0.0000	4368	0.053	0.863	0.6277	0.0332	**30.124**	4368
Central	0.1250	1.0000	0.1250	0.0000	15229	0.033	0.260	0.8242	0.0268	**37.326**	15229
Total					30698						30698

Appendix III:
Cumulative Percent and Standard Errors (SE) of Pregnancy by Months After Vasectomy, Type of Pregnancy and Estimators (Piece-wise Exponential or Kaplan-Meier Estimator)

Type of Pregnancy	Months after Vasectomy	Piece-wise Exponential Estimates[1]				Kaplan-Meier Estimates	
		Clustered by Women		Clustered by Surgeon			
		Cumulative Percent	SE	Cumulative Percent	SE	Cumulative Percent	SE
Any pregnancy (n=924)							
	3	0.7	0.3	0.7	0.3	0.8	0.3
	6	1.3	0.3	1.3	0.3	1.4	0.4
	12	1.8	0.2	1.8	0.2	1.9	0.5
	24	2.9	0.4	2.9	0.4	3	0.6
	36	4.3	0.6	4.3	0.5	4.9	1
Pregnancies 3 or more months after vasectomy; early pregnancy is censored event (n=924)							
	6	0.6	0.3	0.6	0.3	0.7	0.3
	12	1.1	0.2	1.1	0.2	1.2	0.4
	24	2.2	0.4	2.2	0.4	2.3	0.5
	36	3.6	0.6	3.6	0.5	4.2	0.9
All Pregnancies excluding those with no known dates of conception (n=921)							
	6	0.5	0.2	0.5	0.2	0.5	0.2
	12	1.1	0.2	1.1	0.2	1.1	0.3
	24	1.9	0.3	1.9	0.4	2	0.5
	36	3.1	0.5	3.1	0.3	3.6	0.8
All pregnancies excluding early pregnancies and with those no dates of conception (n=914)							
	6	0.5	0.2	0.5	0.2	0.5	0.2
	12	1.1	0.2	1.1	0.2	1.1	0.3
	24	1.9	0.3	1.9	0.4	2	0.5
	36	3.1	0.5	3.1	0.3	3.6	0.8
All pregnancies excluding early pregnancies (n=917)							
	6	0.6	0.3	0.6	0.3	0.7	0.3
	12	1.1	0.2	1.1	0.2	1.2	0.4
	24	2.2	0.4	2.2	0.4	2.3	0.5
	36	3.6	0.6	3.6	0.5	4.2	0.9

[1] To assess the effect of clustering on variance estimates, we considered two approaches. In approach 1, we considered women to contribute woman years to various pregnancy intervals and in approach 2, we considered only that women (indirectly through their husbands) were clustered within surgeons.

Appendix IV: Statistical Tables

Table A.1.
Distribution of Nepal Vasectomy Population (1996-1999) by Development Region

	Development Region				
	Western Region	Eastern Region	Far-West Region	Central Region	Total
Size of Vasectomy Population	9120	3294	4444	16398	33256
Size of Vasectomy Population within Area	7958	3143	4368	15229	30698
Size of First Vasectomy Population	7860	3116	4345	15159	30480
Percent Distribution of First Vasectomy Population	25.8%	10.2%	14.3%	49.7%	100.0
Total Number of Districts	10	8	6	6	32
Number of Districts Randomly Selected	1	1	1	1	4
Number of Vasectomies in Selected Districts	1412	456	639	533	3040
Number of Sample Vasectomies Selected and Fielded	385	152	231	495	1263

Table A.2
Disposition Status of Fielded Sample by District
(Unweighted Counts)

Status of Study Participants	Districts									
	Western District (Tanahu)		Eastern District (Bhojpur)		Far West District (Doti)		Central District (Ramechap)		All Districts	
	n	%	n	%	n	%	n	%	n	%
Interview and Vasectomy Status										
Total Fielded[1]	385	30.5	152	12.0	231	18.3	495	39.2	1263	100.0
Located and Interviewed	322	83.6	117	76.5	187	81.3	434	87.7	1060	83.9
First vasectomy and interviewed	317	82.3	115	75.2	186	121.6	432	87.3	1050	83.1
Repeat vasectomy with interview referring to first vasectomy	1	0.3	1	0.7	.	.	.	.	2	0.2
Repeat vasectomy with interview referring to repeat vasectomy	4	1.0	1	0.7	1	0.7	2	0.4	8	0.6
Not Located	63	16.4	36	23.5	43	28.1	61	12.3	203	16.1
Status of Semen Specimen Among Interviewed Men										
First Vasectomies with Semen Specimen	289	87.3	122	88.4	154	90.1	406	96.7	971	91.6
Sufficient specimen	280	84.6	94	68.1	144	104.3	406	96.7	924	87.2
Invalid laboratory test	1	0.3	1	0.7	.	.	.	.	2	0.2
Uncertain specimen	1	0.3	.	.	.	.	.	.	1	0.1
Insufficient to determine concentration	7	2.1	27	19.6	10	7.2	.	.	44	4.2
First Vasectomies With No Semen Specimen	36	10.9	14	10.1	15	10.9	14	3.3	79	7.5
Repeat Vasectomies with Sufficient Semen Specimen	5	1.5	2	1.4	2	1.4	.	.	9	0.8
Repeat Vasectomies With No Semen Specimen	1	0.3	.	.	.	.	.	.	1	0.1

Table A.2
Disposition Status of Fielded Sample by District (continued)
(Unweighted Counts)

Status of Study Participants	Districts									
	Western District (Tanahu)		Eastern District (Bhojpur)		Far West District (Doti)		Central District (Ramechap)		All Districts	
	n	%	n	%	n	%	n	%	n	%
In Primary Analysis Population	280	87.0	94	81.0	144	76.6	406	93.5	924	87.2
Excluded from Primary Analysis Population	42	13.0	22	19.0	44	37.9	28	6.5	136	12.8
In Interview Analysis Population	318	98.8	115	99.1	187	99.5	432	99.5	1052	99.2
Excluded from Interview Analysis Population	4	1.2	1	0.9	1	0.9	2	0.5	8	0.8
Provided Semen Specimen Regardless of Vasectomy Status	288	100.0	100	100.0	172	100.0	420	100.0	980	100.0
In Laboratory Sensitivity/Specificity Analysis	285	99.0	92	92.0	145	145.0	408	97.1	930	94.9
No VasMarq Reading	2	0.7	1	1.0	.	.	.	.	3	0.3
With VasMarq Readings But no sperm concentration	1	0.3	7	7.0	27	27.0	12	2.9	47	4.8

Figure 1: Study Disposition Status of Fielded Sample

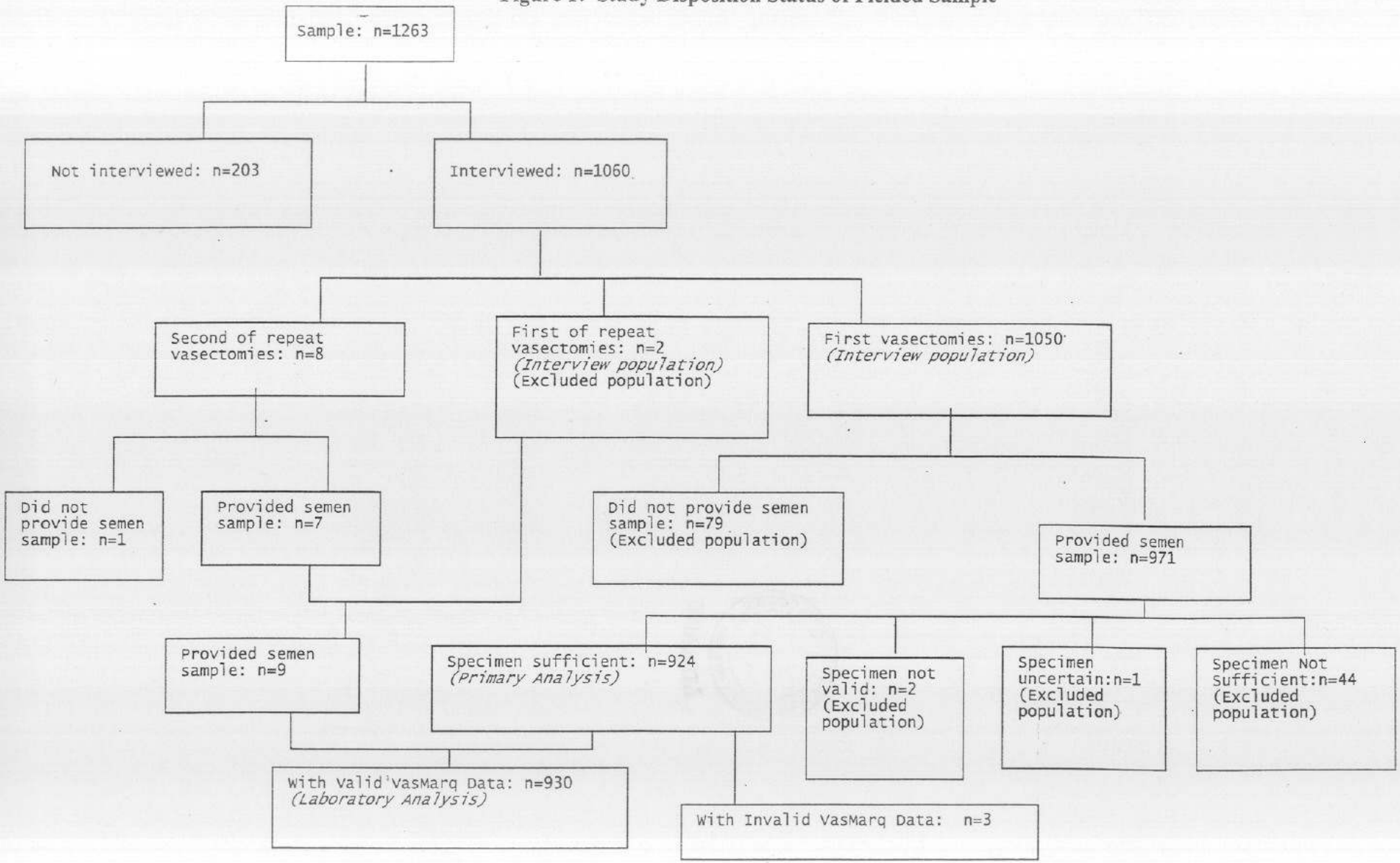

Table A.3.1
Unweighted Counts and Percents and Weighted Percents for Selected Demographic Characteristics of Study Participants by Analysis Populations

Demographic Characteristics	Interview population (n=1052)			Primary analysis population (n=924)			Excluded (n=128)		
	n	(%)	Weighted (%)	n	(%)	Weighted (%)	n	(%)	Weighted (%)
At time of Interview:									
Current Marital Status									
Married	1048	(99.6)	(99.6)	921	(99.7)	(99.7)	127	(99.2)	(99.3)
Widowed	2	(0.2)	(0.2)	1	(0.1)	(0.1)	1	(0.8)	(0.7)
Divorced/Separated	2	(0.2)	(0.2)	2	(0.2)	(0.2)	0	(0.0)	(0.0)
Never Married	0	(0.0)	(0.0)	0	(0.0)	(0.0)	0	(0.0)	(0.0)
Level of Education									
No schooling	194	(18.4)	(19.0)	158	(17.1)	(17.6)	36	(28.1)	(28.8)
Some Primary*	442	(42.0)	(41.0)	388	(42.0)	(41.3)	54	(42.2)	(41.7)
Some secondary	211	(20.1)	(19.7)	190	(20.6)	(20.3)	21	(16.4)	(15.5)
High School and above	204	(19.4)	(20.1)	187	(20.2)	(20.7)	17	(13.3)	(14.0)
Occupation									
Farming	682	(64.8)	(64.5)	593	(64.2)	(64.2)	89	(69.5)	(68.8)
Non-agricultural	369	(35.1)	(35.4)	330	(35.7)	(35.7)	39	(30.5)	(31.2)
At time of Vasectomy:									
Respondent's Age									
18-25	118	(11.2)	(11.5)	110	(11.9)	(11.9)	8	(6.2)	(6.4)
26-30	367	(34.9)	(35.5)	340	(36.8)	(37.0)	27	(21.1)	(21.0)
31-35	327	(31.1)	(31.2)	273	(29.6)	(29.8)	54	(42.2)	(42.4)
>35	240	(22.8)	(21.8)	201	(21.8)	(21.3)	39	(30.5)	(30.2)

* combines non-formal literacy classes and primary

Table A.3.1
Unweighted Counts and Percents and Weighted Percents for Selected Demographic Characteristics of Study Participants by Analysis Populations (continued)

Demographic Characteristics	Interview population (n=1052)			Primary analysis population (n=924)			Excluded (n=128)		
	n	(%)	Weighted (%)	n	(%)	Weighted (%)	n	(%)	Weighted (%)
Wife's Age									
18-27	509	(48.4)	(48.3)	461	(49.9)	(49.5)	48	(37.5)	(37.7)
28-33	389	(37.0)	(37.2)	334	(36.2)	(36.5)	55	(43.0)	(42.6)
>33	146	(13.9)	(13.7)	122	(13.2)	(13.2)	24	(18.8)	(19.0)
Total Number of Children									
Mean (sd)	3.6 (1.43)			3.6 (1.40)			4.2 (1.54)		
Median	3			3			4		
Range	0[1]-9			0[1]-9			1-9		
Number of Sons									
Mean (sd)	2.1 (0.94)			2.0 (0.89)			2.4 (1.15)		
Median	2			2			2		
Range	0-7			0-5			1-7		
Number of Daughters									
Mean (sd)	1.6 (1.20)			1.6 (1.20)			1.7 (1.18)		
Median	1			1			2		
Range	0-7			0-7			0-6		

[1] Two participants had no children at time of vasectomy.

Table A.3.1
Unweighted Counts and Percents and Weighted Percents for Selected Demographic Characteristics of Study Participants by Analysis Populations (continued)

Characteristics	Interview population (n=1052)	Primary analysis population (n=924)	Excluded (n=128)
At time of Vasectomy:			
Respondent's Age			
Mean (sd)	32.1 (5.99)	31.8 (5.90)	34.1 (6.28)
Median	31	31	33
Range	19-60	19-54	21-60
Wife's Age			
Mean (sd)	28.0 (4.83)	27.8 (4.76)	29.3 (5.16)
Median	28	27	29
Range	18-47	18-45	20-47

Table A.3.2.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Contraceptive History and Counseling Information of Study Participants by Analysis Populations

Characteristic	Interview population n=1052			Primary analysis population n=924			Excluded n=128		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Told to Use Condoms or Other Back-up Method?									
No	88	(8.4)	(8.5)	72	(7.8)	(7.8)	16	(12.5)	(13.0)
Yes	963	(91.5)	(91.4)	851	(92.1)	(92.1)	112	(87.5)	(87.0)
Reported back-up use	928	(88.2)	(88.2)	820	(88.7)	(88.9)	108	(84.4)	(83.9)
Did not report back-up use	35	(3.3)	(3.2)	31	(3.4)	(3.2)	4	(3.1)	(3.0)
Told to Use Back-up for:									
Time after Vasectomy (Weeks):									
12+ weeks	174	(18.1)	(19.5)	153	(18.0)	(18.9)	21	(18.8)	(19.2)
5-11 weeks	38	(4.0)	(4.3)	36	(4.2)	(4.4)	2	(1.8)	(2.1)
1-4 weeks	323	(33.5)	(35.8)	291	(34.2)	(35.7)	32	(28.6)	(29.5)
Cannot remember	307	(31.9)	(27.0)	260	(30.6)	(27.2)	47	(42.0)	(40.0)
Missing	121	(12.6)	(13.3)	111	(13.0)	(13.8)	10	(8.9)	(9.2)
Told to Use Back-up Until Having Number of Ejaculations after Vasectomy:									
20	236	(24.5)	(20.7)	201	(23.6)	(21.2)	35	(31.2)	(29.5)
30	143	(18.8)	(15.2)	128	(15.0)	(15.5)	15	(13.4)	(13.8)
Other	66	(6.8)	(6.3)	58	(6.8)	(6.4)	8	(7.1)	(7.3)
Cannot remember	175	(18.2)	(16.0)	144	(16.9)	(15.1)	31	(27.7)	(25.5)
Missing	343	(35.6)	(41.8)	320	(37.6)	(41.9)	23	(20.5)	(23.9)

Table A.3.2.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Contraceptive History and Counseling Information of Study Participants by Analysis Populations (continued)

Characteristic	Interview population n=1052			Primary analysis population n=924			Excluded n=128		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Told to Use Back-up for:									
Number of Weeks and Ejaculations after Vasectomy:									
12+ weeks and 20+ ejaculations	7	(0.7)	(0.8)	5	(0.6)	(0.6)	2	(1.8)	(2.0)
12+ weeks only	166	(12.2)	(18.6)	147	(17.3)	(18.1)	19	(17.0)	(17.2)
5-11 weeks only	37	(3.8)	(4.2)	35	(4.1)	(4.3)	2	(1.8)	(2.1)
1-4 weeks only	280	(29.1)	(31.5)	251	(29.5)	(31.0)	29	(25.9)	(26.6)
20+ ejaculations only	334	(34.7)	(31.3)	389	(34.0)	(32.0)	45	(40.2)	(38.4)
Other	104	(10.8)	(10.1)	93	(10.9)	(10.5)	11	(9.8)	(10.1)
Missing	2	(0.2)	(0.2)	2	(0.2)	(0.2)	0	(0.0)	(0.0)
Cannot remember	33	(3.4)	(3.3)	29	(3.4)	(3.2)	4	(3.6)	(3.5)
Were you given condoms?									
Yes	896	(85.2)	(83.3)	785	(85.0)	(83.6)	111	(86.7)	(85.7)
No	155	(14.7)	(16.6)	138	(14.9)	(16.3)	17	(13.3)	(14.3)

Table A.3.2.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Contraceptive History and Counseling Information of Study Participants by Analysis Populations (continued)

Characteristic	Interview population N=1052			Primary analysis population N=924			Excluded N=128		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Contraceptive Use 3 months Prior to Vasectomy:									
Wife was pregnant	173	(16.4)	(16.9)	149	(16.1)	(16.6)	24	(18.8)	(18.8)
Just had a baby	82	(7.8)	(8.4)	70	(7.6)	(8.0)	12	(9.4)	(9.6)
Breastfeeding	16	(1.5)	(1.7)	15	(1.6)	(1.8)	1	(0.8)	(0.8)
Male Condoms	136	(12.9)	(12.2)	122	(13.2)	(12.6)	14	(10.9)	(10.5)
Injectables	178	(16.9)	(17.6)	161	(17.4)	(18.0)	17	(13.3)	(13.6)
Implants	4	(0.4)	(0.3)	4	(0.4)	(0.4)	0	(0.0)	(0.0)
IUD	5	(0.5)	(0.4)	5	(0.5)	(0.5)	0	(0.0)	(0.0)
Pill	24	(2.3)	(2.2)	18	(2.0)	(2.0)	6	(4.7)	(4.4)
Diaphragm, etc.	1	(0.1)	(0.1)	1	(0.1)	(0.1)	0	(0.0)	(0.0)
No sexual contact	2	(0.2)	(0.2)	2	(0.2)	(0.2)	0	(0.0)	(0.0)
Periodic Abstinence	6	(0.6)	(0.6)	6	(0.7)	(0.7)	0	(0.0)	(0.0)
No modern method	569	(54.1)	(52.8)	491	(53.1)	(52.1)	78	(60.9)	(60.4)

Table A.3.2.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Contraceptive History and Counseling Information of Study Participants by Analysis Populations (continued)

Characteristic	Interview population N=1052			Primary analysis population N=924			Excluded N=128		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Contraceptive Use 3 months After Vasectomy:									
Wife was pregnant	109	(10.4)	(10.9)	97	(10.5)	(11.0)	12	(9.4)	(9.6)
Just had a baby	77	(7.3)	(8.0)	65	(7.0)	(7.6)	12	(9.4)	(9.9)
Breastfeeding	8	(0.8)	(0.8)	4	(0.4)	(0.4)	4	(3.1)	(3.3)
Male Condoms	539	(51.2)	(50.2)	474	(51.3)	(50.9)	65	(50.8)	(50.1)
Injectables	45	(4.3)	(4.7)	40	(4.3)	(4.6)	5	(3.9)	(4.2)
Implants	2	(0.2)	(0.2)	2	(0.2)	(0.2)	0	(0.0)	(0.0)
IUD	0	(0.0)	(0.0)	0	(0.0)	(0.0)	0	(0.0)	(0.0)
Pill	1	(0.1)	(0.1)	1	(0.1)	(0.1)	0	(0.0)	(0.0)
Diaphragm, etc.	0	(0.0)	(0.0)	0	(0.0)	(0.0)	0	(0.0)	(0.0)
No sexual contact	65	(6.2)	(7.2)	59	(6.4)	(7.1)	6	(4.7)	(5.4)
Periodic Abstinence	6	(0.6)	(0.6)	6	(0.7)	(0.6)	0	(0.0)	(0.0)

Table A.3.2.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Contraceptive History and Counseling Information of Study Participants by Analysis Populations (continued)

Characteristic	Interview population N=1052			Primary analysis population N=924			Excluded N=128		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Ever Used a Male Condom									
Yes	652	62.0	60.9	571	61.8	61.4	81	63.3	62.7
No	400	38.0	39.1	353	38.2	38.6	47	36.7	37.3
Used Condom Since Vasectomy: As a back-up method to prevent pregnancy									
Yes	550	83.2	83.1	483	84.0	84.0	67	77.9	78.3
No	111	16.8	16.9	92	16.0	16.0	19	22.1	21.7
As a method to protect against disease									
Yes	15	2.3	2.2	12	2.1	2.0	3	3.7	3.7
No	637	97.7	97.8	558	97.9	98.0	79	96.3	96.3

Table A.3.3
Counseling Information by Year of Vasectomy
Primary Analysis Population

Characteristic	1996		1997		1998		1999		Total	
	n	%	n	%	n	%	n	%	n	%
Told about effectiveness of vasectomy for prevention of pregnancy										
Completely reliable	101	9.6	161	15.3	175	16.6	43	4.1	480	45.6
Not completely reliable	49	4.7	54	5.1	56	5.3	24	2.3	183	17.4
Other	0	0.0	2	0.2	2	0.2	0	0.0	4	0.4
Nothing about effectiveness/reliability	71	6.8	106	10.1	117	11.1	22	2.1	316	30.0
Cannot remember	4	0.4	38	3.6	19	1.8	8	0.8	69	6.6
Told to Use Condoms?										
No	23	2.2	25	2.4	31	3.0	9	0.9	88	8.4
Yes	202	19.2	336	32.0	337	32.1	88	8.4	963	91.6
Back-up Use Reported for Weeks:										
1-4 weeks	84	10.0	96	11.4	113	13.4	30	3.6	323	38.4
5-11 weeks	8	1.0	13	1.5	13	1.3	6	0.7	38	4.5
12+ weeks	63	7.5	56	6.6	43	5.1	12	1.4	174	20.7
Cannot remember	35	4.2	133	15.8	116	13.8	23	2.7	307	36.5
Ejaculations:										
1-20	21	3.4	118	19.0	100	16.1	25	4.0	264	42.6
21-30	28	4.5	49	7.9	84	13.6	11	1.8	172	27.7
More than 30	2	0.3	4	0.6	2	0.3	1	0.2	9	1.4
Cannot remember	49	7.9	63	10.2	52	8.4	11	1.8	175	28.2
Recalled Correct Guidelines (12+ weeks or at least 20 ejaculations)										
No	100	11.9	124	13.8	142	16.9	44	5.5	410	49.3
Yes	80	9.6	157	18.8	164	18.7	40	4.7	441	50.7

Table A.3.4.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Site, Surgeon and Couple Characteristics by Analysis Populations

Characteristics	Interview population (n=1052)			Primary analysis population (n=924)			Excluded (n=128)		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Service Delivery Point									
Camp	963	(91.5)	(92.7)	854	(92.4)	(92.8)	109	(85.2)	(85.7)
Other	89	(8.5)	(7.3)	70	(7.6)	(7.2)	19	(14.8)	(14.3)
Surgeon Technique									
Fascial Interposition (FI)									
Yes	114	(10.8)	(9.3)	84	(9.1)	(8.7)	30	(23.4)	(23.2)
No	938	(89.2)	(90.7)	840	(90.9)	(91.3)	98	(76.6)	(76.8)
>2 cm vas excision									
Yes	608	(57.8)	(64.3)	546	(59.1)	(63.6)	62	(48.4)	(51.4)
No	444	(42.2)	(35.7)	378	(40.9)	(36.4)	66	(51.6)	(48.6)

Table A.3.4.
Unweighted Counts and Percents and Weighted (Wtd) Percents for Selected Site, Surgeon and Couple Characteristics by Analysis Populations (continued)

Characteristics	Interview population (n=1052)			Primary analysis population (n=924)			Excluded (n=128)		
	n	(%)	Wtd (%)	n	(%)	Wtd (%)	n	(%)	Wtd (%)
Surgeon Technique (continued)									
FI and >2 cm vas excision	92	(8.8)	(7.6)	65	(7.0)	(6.7)	27	(21.1)	(21.0)
FI only	22	(2.1)	(1.7)	19	(2.1)	(1.9)	3	(2.3)	(2.2)
>2 cm vas excision	516	(49.0)	(56.6)	481	(52.1)	(56.8)	35	(27.3)	(30.4)
Neither FI nor >2 cm vas excision	422	(40.1)	(34.1)	359	(38.8)	(34.6)	63	(49.2)	(46.4)
Surgeon Vasectomy Experience									
Above number of vasectomy experience of surgeon 41	330	(31.4)	(27.1)	269	(29.1)	(27.1)	61	(47.7)	(45.9)
Below number of vasectomy of experience of surgeon 41	276	(26.2)	(21.9)	237	(25.6)	(21.9)	39	(30.5)	(28.3)
Vasectomy experience of surgeon 41	432	(41.1)	(49.7)	406	(43.9)	(49.7)	26	(20.3)	(24.1)

Table B.1
Unweighted Counts, Weighted Prevalence and 95% Confidence Interval for Vasectomy Outcome
Based on Laboratory and Interview Data
Primary Analysis Population

Vasectomy Outcomes		Unweighted n	Weighted Estimates		
			Prevalence(%)	95% Confidence Interval	
				Lower	Upper
Laboratory-based					
	With Persistent Sperm	23	2.3	1.1	3.6
	Overt Failure (=>2 million sperm/ml)	18	1.8	0.8	2.9
	Indeterminate (0.5-2 million sperm/ml)	5	0.5	0.2	0.8
	No Persistent Sperm (Presumed Success)	901	97.7	96.4	98.9
Interview- and laboratory-based					
	With Pregnancy Report				
	All pregnancies	32	3.3	1.8	4.8
	Pregnancies 3 or more months after vasectomy	22	2.3	0.7	3.8
	Pregnancies within 3 months of vasectomy	7	0.7	0.2	1.2
	Pregnancies with no date of conception	3	0.3	0.0	0.8
	No Pregnancy Report	892	96.7	95.2	98.2
	With any type of failure[1]				
	All pregnancies	40	4.1	2.3	5.9
	Pregnancies 3 or more months after vasectomy or pregnancies with no known date of conception	33	3.4	1.4	5.4
	Pregnancies 3 or more months after vasectomy	30	3.1	1.1	5.1
	No failure	884	95.9	94.1	97.7

[1] With persistent sperm or pregnancy

Table B.2
Unweighted Counts and Weighted (Wtd.) Percents for Concordance of Vasectomy Outcome
Based on Laboratory Results and Pregnancy Reports
Primary Analysis Population

Laboratory Results	Pregnancy Reports									
	No Pregnancy		With Pregnancy						All	
			Pregnancy 3 or more months after vasectomy		Pregnancy within 3 months of vasectomy		Pregnancy with no known date of conception			
	n	Wtd. %	n	Wtd. %	n	Wtd. %	n	Wtd. %	n	Wtd. %
Presumed Success	884	(95.9)	11	(1.2)	6	(0.6)	0	(0.0)	901	(97.7)
Indeterminate	3	(0.3)	1	(0.1)	0	(0.0)	1	(0.1)	5	(0.5)
Overt Failure	5	(0.5)	10	(1.0)	1	(0.1)	2	(0.2)	18	(1.8)
All	892	(96.7)	22	(2.3)	7	(0.7)	3	(0.3)	924	(100.0)
Kappa Statistics:[1]										
Persistent Sperm and All Reported Pregnancies	0.532									
Persistent Sperm and Pregnancies 3 or more months after vasectomy	0.476									

[1] Kappa statistics are for agreement of dichotomous persistent sperm measures and dichotomous pregnancy reports.

Figure 2

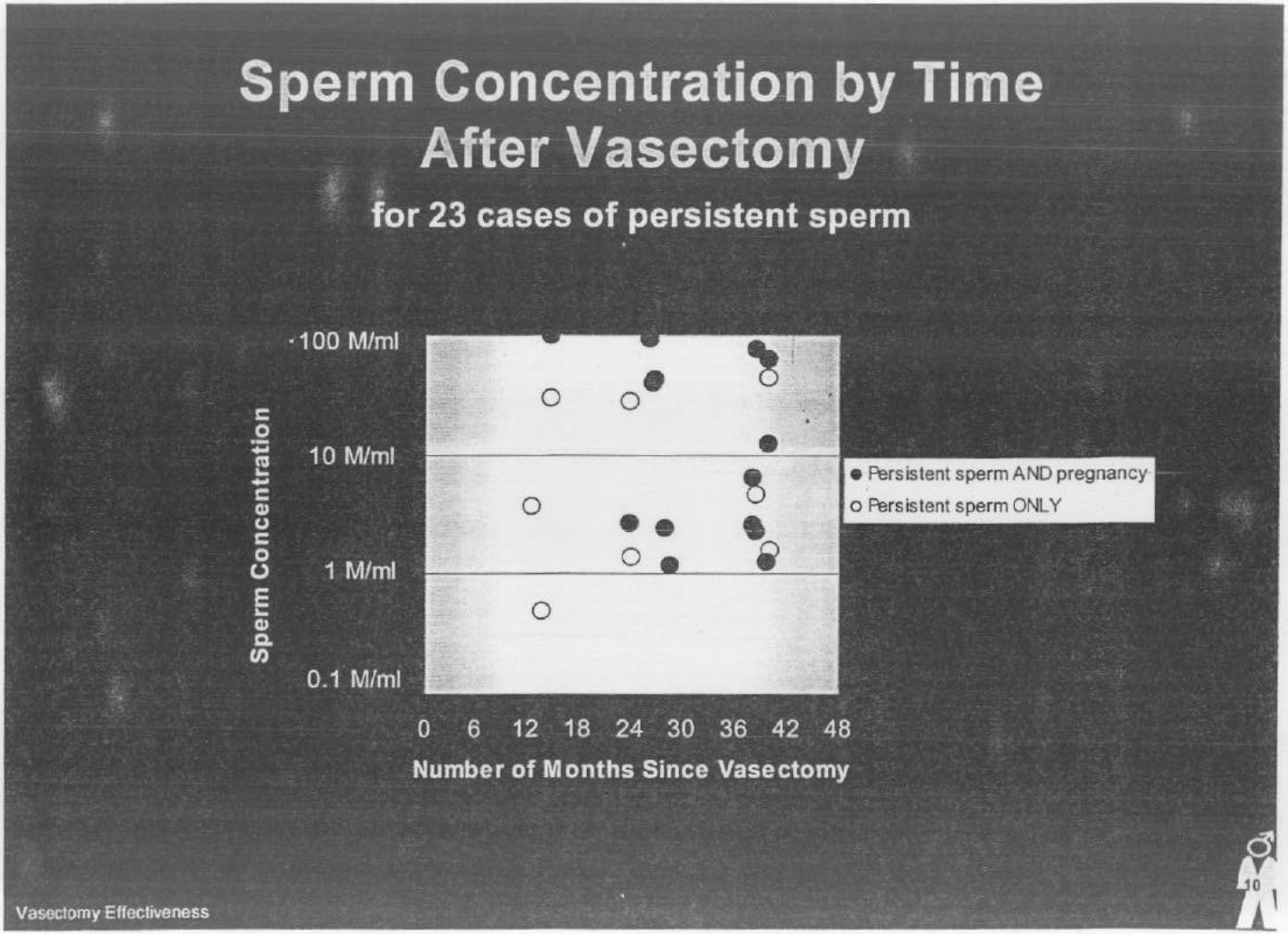
Sperm Concentration by Time After Vasectomy
for 23 cases of persistent sperm
100 M/ml
10 M/ml
1 M/ml
0.1 M/ml
Sperm Concentration
0 6 12 18 24 30 36 42 48
Number of Months Since Vasectomy
Persistent sperm AND pregnancy
Persistent sperm ONLY
Vasectomy Effectiveness

Figure 3
Proportion of Men Having Persistent
Sperm by Year After Vasectomy
(weighted estimates, n=924)

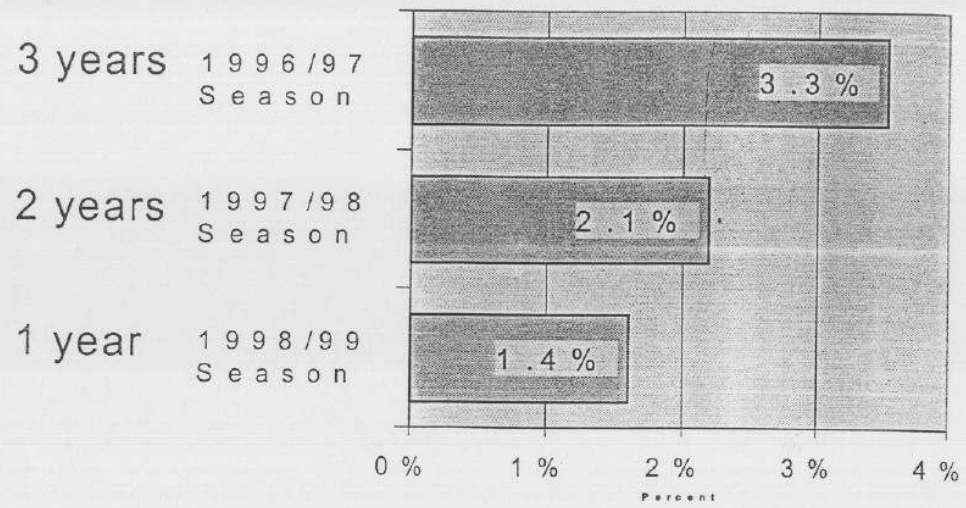

Table B.3
Cumulative Probability of Pregnancy[1] Based on Pregnancies within and after 3 months of Vasectomy, Standard Error (SE) and 95% Confidence Interval by Months Since Vasectomy
Primary Analysis Population

Timing of Pregnancies Included as Event	Months Since Vasectomy	Probability of Pregnancy per 100 Women	SE	95% Confidence Interval for Pregnancy	
All pregnancies[2]					
	3	0.7	0.3	0.2	1.2
	6	1.3	0.3	0.8	1.8
	12	1.8	0.2	1.4	2.3
	24	2.9	0.4	2.1	3.6
	36	4.3	0.6	3.1	5.4
Pregnancies 3 or more months after vasectomy[3]					
	6	0.5	0.2	0.1	1.0
	12	1.1	0.2	0.6	1.5
	24	1.9	0.3	1.3	2.6
	36	3.1	0.5	2.1	4.2

1 This is probability of reporting pregnancy per 100 women
2 Include 3 women with imputed days of conception.
3 Exclude 7 women with pregnancies within 3 months of vasectomy and 3 women with no dates of conception

Figure 4

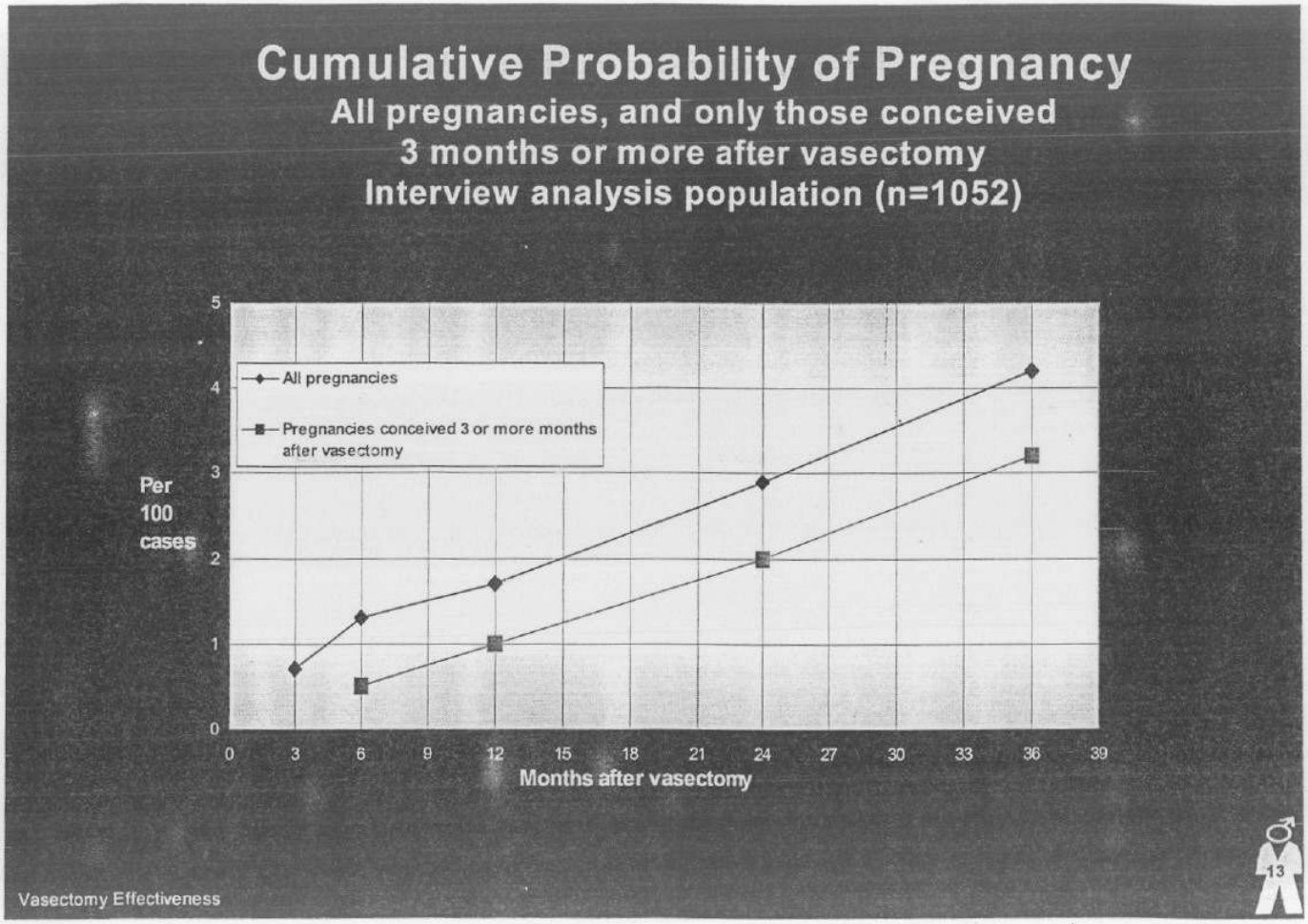
Cumulative Probability of Pregnancy
All pregnancies, and only those conceived
3 months or more after vasectomy
Interview analysis population (n=1052)
All pregnancies
Pregnancies conceived 3 or more months after vasectomy
Per 100 cases
0
1
2
3
4
5
0 3 6 9 12 15 18 21 24 27 30 33 36 39
Months after vasectomy
Vasectomy Effectiveness
13

Table B.4
Unweighted Number of Sample and Events and Weighted (Wtd) Prevalence of Vasectomy Failure Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples
Primary Analysis Population

Selected Characteristics	Prevalence of Vasectomy Failure Using Alternative Measures											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd %	n	# of Failures	Wtd %
Type of Service Delivery Point												
Camp	854	15	1.7	854	20	2.2	854	34	3.8	854	29	3.3
Others	70	3	4.1	70	3	4.1	70	6	8.3	70	4	5.5
Surgeon Technique*Age of Respondent												
Fascial Interposition												
<= 30 years old	32	3	9.3	32	4	12.6	32	4	12.6	32	4	12.6
> 30 years old	52	4	7.4	52	4	7.4	52	5	9.4	52	4	7.6
No Fascial Interposition												
<= 30 years old	418	6	1.4	418	10	2.2	418	20	4.5	418	18	4.1
> 30 years old	422	5	1.1	422	5	1.1	422	11	2.5	422	7	1.6

Table B.4
Unweighted Number of Sample and Events and Weighted (Wtd) Prevalence of Vasectomy Failure Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples
Primary Analysis Population (continued)

Selected Characteristics	Prevalence of Vasectomy Failure Using Alternative Measures											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %
Surgeon Technique												
Fascial Interposition (FI)												
Yes	84	7	8.1	84	8	9.4	84	9	10.6	84	8	9.5
No	840	11	1.3	840	15	1.7	840	31	3.5	840	25	2.8
> 2 cm vas excision												
Yes	546	7	1.2	546	8	1.4	546	16	2.8	546	12	2.1
No	378	11	3.0	378	15	4.1	378	24	6.4	378	21	5.6
FI and/or > 2 cm incision												
FI and >2 cm incision	65	5	7.4	65	6	9.0	65	7	10.6	65	6	9.2
FI only	19	2	10.5	19	2	10.5	19	2	10.5	19	2	10.5
>2cm vas excision only	481	2	0.4	481	2	0.4	481	9	1.8	481	6	1.3
Neither FI nor >2 cm vas excision	359	9	2.6	359	13	3.7	359	22	6.2	359	19	5.4

Table B.4

Unweighted Number of Sample and Events and Weighted (Wtd) Prevalence of Vasectomy Failure Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples
Primary Analysis Population (continued)

Selected Characteristics	Prevalence of Vasectomy Failure Using Alternative Measures											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %
Surgeon Vasectomy Experience												
Above number of vasectomy experience of surgeon 41	269	13	5.0	269	17	6.5	269	23	8.7	269	20	7.6
Below number of vasectomy of experience of surgeon 41	237	3	1.3	237	4	1.7	237	10	4.3	237	7	3.0
Vasectomy experience of surgeon 41	406	2	0.5	406	2	0.5	406	7	1.7	406	6	1.5
Respondent's age												
18-25	110	5	4.5	110	7	6.1	110	10	8.4	110	9	7.6
26-30	340	4	1.1	340	7	1.9	340	14	4.0	340	13	3.7
31-35	273	4	1.3	273	4	1.3	273	10	3.5	273	7	2.4
Over 35	201	5	2.4	201	5	2.4	201	6	2.9	201	4	2.0
Wife's Age												
18-27	461	12	2.5	461	16	3.3	461	26	5.3	461	23	4.7
28-33	334	5	1.4	334	6	1.7	334	12	3.5	334	9	2.6
over 34	122	1	0.8	122	1	0.8	122	1	0.8	122	1	0.8

Table B.4

Unweighted Number of Sample and Events and Weighted (Wtd) Prevalence of Vasectomy Failure Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples Primary Analysis Population (continued)

Selected Characteristics	Prevalence of Vasectomy Failure Using Alternative Measures											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %	n	# of Failures	Wtd. %
Wife's age												
18-22	110	3	2.3	110	5	3.4	110	7	5.7	110	7	5.7
23-27	351	9	2.5	351	11	3.1	351	19	5.2	351	16	4.4
28-32	310	5	1.5	310	6	1.8	310	12	3.8	310	9	2.8
33-37	110	1	0.9	110	1	0.9	110	1	0.9	110	1	0.9
38-42	30	0	0.0	30	0	0.0	30	0	0.0	30	0	0.0
43-47	6	0	0.0	6	0	0.0	6	0	0.0	6	0	0.0

Table B.5
Odds Ratios and 95% Confidence Interval for Vasectomy Failures Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples
Primary Analysis Population

Selected Characteristics	Measures of Vasectomy Failure											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit
Type of Service Delivery Point												
Camp	0.4	0.1	1.1	0.5	0.2	1.5	0.4	0.2	1.2	0.6	0.1	2.5
Others	1.0											
Surgeon Technique												
Fascial Interposition (FI)												
Yes	7.0	2.1	23.5	4.6	2.3	9.2	2.8	1.5	5.2	3.5	1.6	7.9
No	1.0											
> 2 cm vas excision												
Yes	0.4	0.1	2.1	0.2	0.1	0.9	0.4	0.1	1.1	0.3	0.1	1.6
No	1.0											

Table B.5
Odds Ratios and 95% Confidence Interval for Vasectomy Failures Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples
Primary Analysis Population (continued)

Selected Characteristics	Measures of Vasectomy Failure											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit
Surgeon Technique												
FI and/or > 2 cm incision												
Both FI and > 2 cm excision	3.0	0.7	12.9	1.8	0.9	3.7	1.4	0.9	2.4	1.7	1.0	3.1
FI only	4.4	2.1	9.1	2.7	1.4	5.4	1.7	1.1	2.4	2.0	1.3	3.2
>2 cm excision only	0.2	0.0	1.8	0.1	0.0	1.1	0.3	0.1	1.3	0.2	0.0	2.4
Neither FI nor >2 cm	1.0			1.0			1.0			1.0		
Surgeon Vasectomy Experience*												
Above vasectomy experience of surgeon 41	10.8	1.0	115.5	7.4	1.5	36.6	4.4	0.9	20.5	5.0	0.6	39.4
Below vasectomy experience of surgeon 41	2.7	0.2	30.5	2.0	0.3	12.3	2.2	0.4	12.2	1.9	0.2	16.8
Vasectomy experience of surgeon 41	1.0			1.0			1.0			1.0		

Table B.5
Odds Ratios and 95% Confidence Interval for Vasectomy Failures Using Alternative Measures of Failure by Selected Characteristics of Site, Surgeon and Couples
Primary Analysis Population (continued)

Selected Characteristics	Measures of Vasectomy Failure											
	Overt Failure (>= 2 mil sperm/ml)			Persistent Sperm (>=0.5 mil sperm/ml)			Any evidence of failure (persistent sperm or any pregnancy)			Any evidence of failure (persistent sperm or pregnancy 3 or more months after vasectomy)		
	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit
Respondent's age at vasectomy												
18-25	1.9	0.4	10.1	2.6	0.5	12.8	3.1	0.8	11.3	4.1	0.7	23.5
26-30	0.5	0.2	1.2	0.8	0.3	2.2	1.4	0.6	3.3	1.9	0.6	6.4
31-35	0.5	0.1	2.1	0.5	0.1	2.1	1.2	0.4	4.2	1.2	0.2	6.8
Over 35	1.0			1.0			1.0			1.0		
Wife's Age at vasectomy												
18-27	3.1	0.3	28.9	4.1	0.5	34.7	6.7	0.8	56.8	6.0	0.7	51.7
28-33	1.7	0.5	6.6	2.0	0.5	8.9	4.4	0.7	29.3	3.3	0.5	20.9
over 34	1.0			1.0			1.0			1.0		

Table B.6.
Odds Ratios and 95% Confidence Interval (CI) from Multivariable Logistic Models for Persistent Sperm and Pregnancies 3 or More Months After Vasectomy
Primary Analysis Population

Covariates	Persistent Sperm [1] (=>2 mil sperm/ml)			Pregnancies 3 or more months after vasectomy [2]		
		95 % CI			95% CI	
	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit
Surgeon Technique						
> 2 cm vas excision						
Yes	0.3	0.1	0.8	0.3	0.1	0.9
No	1.0			1.0		
Fascial Interposition						
Yes	2.7	0.7	11.0	2.9	0.6	12.9
No	1.0			1.0		
Special technique due to surgeon 41						
Yes	0.4	0.0	3.7	0.8	0.1	9.3
No	1.0			1.0		
Surgeon Experience per 100 completed vasectomies	1.0	1.0	1.0	1.0	1.0	1.0

[1] Twelve observations with missing data on surgeon experience were excluded in fitting this model.
[2] Seven pregnancies within three months of vasectomy were coded as non-event in this model. Nineteen observations (12 with missing surgeon experience and seven with missing age of wife) were excluded in fitting this model.

Table B.6.
Odds Ratios and 95% Confidence Interval (CI) from Multivariable Logistic Models for Persistent Sperm and Pregnancies 3 or More Months After Vasectomy
Primary Analysis Population (continued)

Covariates	Persistent Sperm[1] (=>2 mil sperm/ml)			Pregnancies 3 or more months after vasectomy[2]		
		95 % CI			95% CI	
	Odds Ratio	Lower Limit	Upper Limit	Odds Ratio	Lower Limit	Upper Limit
Age[3]						
of study participants in 5-year intervals	0.6	0.3	1.2	N/A	N/A	N/A
of wives of study participants in 5-year intervals	N/A	N/A	N/A	0.5	0.3	0.9

[1] Twelve observations with missing data on surgeon experience were excluded in fitting this model.
[2] Seven pregnancies within three months of vasectomy were coded as non-event in this model. Nineteen observations (12 with missing surgeon experience and seven with missing age of wife) were excluded in fitting this model.
[3] Age of study participants was a predictor for persistent sperm count and age of wives of study participant was a predictor for pregnancy.

Percent Reporting Pregnancy

3 or more months after Vasectomy

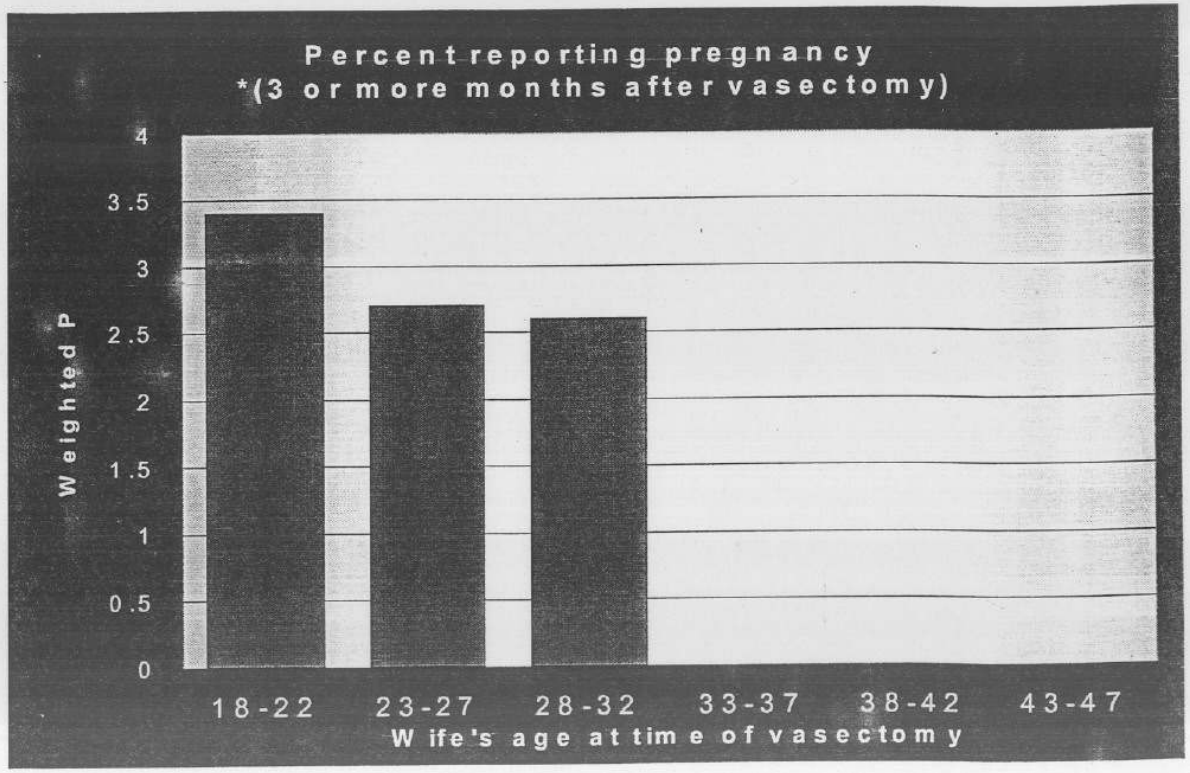

Table C.1
Unweighted Counts, Weighted Proportion and 95% Confidence Interval for Vasectomy Outcome Based on Pregnancy Reports:
Interview Analysis Population

Vasectomy Outcomes		Unweighted n	Weighted Estimates		
			Proportion	95% Confidence Interval	
				Lower	Upper
Interview-based					
	Pregnancy Report				
	All pregnancies	38	3.3	1.8	4.8
	Pregnancies 3 or more months after vasectomy	27	2.3	0.8	3.8
	Pregnancies within 3 months of vasectomy	8	0.7	0.2	1.2
	Pregnancies with no date of conception	3	0.3	0.0	0.7
	No Pregnancy Report	1014	96.7	95.2	98.2

Table C.2
Cumulative Probability of Pregnancy[1] Based on Pregnancies (within and after 3 months of Vasectomy) Standard Error (SE) and 95% Confidence Interval by Months Since Vasectomy: Interview Analysis Population

Timing of Pregnancies Included as Event	Months Since Vasectomy	Probability of Pregnancy per 100 Women[1]	SE	95% Confidence Interval for Pregnancy	
All pregnancies[2]					
	3	0.7	0.2	0.2	1.1
	6	1.3	0.2	0.8	1.8
	12	1.7	0.2	1.4	2.1
	24	2.9	0.3	2.2	3.5
	36	4.2	0.5	3.2	5.2
Pregnancies 3 or more months after vasectomy					
	6	0.5	0.2	0.1	1.0
	12	1.0	0.2	0.6	1.4
	24	2.0	0.3	1.4	2.6
	36	3.2	0.5	2.2	4.1

1 This is probability of reporting pregnancy per 100 women.
2 Include 3 women with imputed dates of conception.

Table D.1
Sensitivity/Specificity and Predictive Propertiesof Vasmarq Results
Relative to Two Sperm Concentration Cut-off Values for Vasectomy Failure
Laboratory Analysis Population (Unweighted Counts)

First Cut-off	Sperm Concentration Cut-off Values (Gold Standard)	Vasmarq Results[1]		Total
		Positive	Negative	
	Overt Failure (=>2 mil/ml sperm conc.)	9	9	18
	Presumed Success or indeterminate (less than 2 mil/ml sperm conc.)	33	879	912
	Total	42	888	930
	Sensitivity:	50.0		
	Specificity:	96.4		
	Positive Predictive Value:	21.4		
	Negative Predictive Value:	99.0		
Second Cut-off	**Sperm Concentration Cut-off Values (Gold Standard)**	**Vasmarq Results**		**Total**
		Positive	Negative	
	Persistent Sperm (=>0.5 mil/ml sperm conc.)	9	14	23
	Presumed Success (less than 0.5 mil/ml sperm conc.)	33	874	907
	Total	42	888	930
	Sensitivity:	39.1		
	Specificity:	96.4		
	Positive Predictive Value:	21.4		
	Negative Predictive Value:	98.4		

[1] Indeterminate Vasmarq result is considered negative.

Table D.1
Sensitivity/Specificity and Predictive Properties of Vasmarq Results
Relative to Two Sperm Concentration Cut-off Values for Vasectomy Failure (continued)
Laboratory Analysis Population (Unweighted Counts)

Third Cut-off	Sperm Concentration Cut-off Values (Gold Standard)	Vasmarq Results[2]		Total
		Positive	Negative	
	=>5 mil/ml sperm conc.	9	3	12
	Less than 5 mil/ml sperm conc.	33	885	918
	Total	42	888	930
	Sensitivity:	75.0		
	Specificity:	96.4		
	Positive Predictive Value:	21.4		
	Negative Predictive Value:	99.7		
Fourth Cut-off	**Sperm Concentration Cut-off Values (Gold Standard)**	**Vasmarq Results**		**Total**
		Positive	Negative	
	=>5 mil/ml sperm conc.	9	2	11
	Less than 5 mil/ml sperm conc.	33	886	919
	Total	42	888	930
	Sensitivity:	81.8		
	Specificity:	96.4		
	Positive Predictive Value:	21.4		
	Negative Predictive Value:	99.8		

[2] Indeterminate Vasmarq result is considered negative.

Table D.1
Sensitivity/Specificity and Predictive Properties of Vasmarq Results
Relative to Two Sperm Concentration Cut-off Values for Vasectomy Failure (continued)
Laboratory Analysis Population (Weighted Counts)

First Cut-off	Sperm Concentration Cut-off Values (Gold Standard)	Vasmarq Results[1]		Total
		Positive	Negative	
	Overt Failure (=>2 mil/ml sperm conc.)	279	287	566
	Presumed Success or indeterminate (less than 2 mil/ml sperm conc.)	1131	29001	30132
	Total	1410	29288	30698
	Sensitivity:	49.3		
	Specificity:	96.2		
	Positive Predictive Value:	19.8		
	Negative Predictive Value:	99.0		
Second Cut-off	**Sperm Concentration Cut-off Values (Gold Standard)**	**Vasmarq Results**		**Total**
		Positive	Negative	
	Persistent Failure (=>0.5 mil/ml sperm conc.)	279	439	718
	Presumed Success (less than 0.5 mil/ml sperm conc.)	1131	28849	29980
	Total	1410	29288	30698
	Sensitivity:	38.9		
	Specificity:	96.2		
	Positive Predictive Value:	19.8		
	Negative Predictive Value:	98.5		

[1] Indeterminate Vasmarq result is considered negative.

Table D.1(continued)
Sensitivity/Specificity and Predictive Properties of Vasmarq Results
Relative to Two Sperm Concentration Cut-off Values for Vasectomy Failure (continued)
Laboratory Analysis Population (Weighted Counts)

Third Cut-off	Sperm Concentration Cut-off Values (Gold Standard)	Vasmarq Results[2]		Total
		Positive	Negative	
	Overt Failure (=>5 mil/ml sperm conc.)	279	99	378
	Presumed Success (less than 5 mil/ml sperm conc.)	1131	29189	30320
	Total	1410	29288	30698
	Sensitivity:	73.7		
	Specificity:	96.3		
	Positive Predictive Value:	19.8		
	Negative Predictive Value:	99.7		
Fourth Cut-off	**Sperm Concentration Cut-off Values (Gold Standard)**	**Vasmarq Results**		**Total**
		Positive	Negative	
	Persistent Failure (=>10 mil/ml sperm conc.)	279	71	350
	Presumed Success (less than 10 mil/ml sperm conc.)	1131	29217	30348
	Total	1410	29288	30698
	Sensitivity:	79.6		
	Specificity:	96.3		
	Positive Predictive Value:	19.8		
	Negative Predictive Value:	99.8		

[2] Indeterminate Vasmarq result is considered negative.

Figure 6

Performance of VasMarq test

		VasMarq Results		
		Positive	Negative	Total
Outcome	Overt failure (≥ 2M/ml)	9	9	18
	Presumed success or indeterminate (<2 M/ml)	33	879	918
	Total	42	888	930

	Sensitivity	*Specificity*
At 2 M/ml	*50%*	*96%*
At 5 M/ml	*75%*	*96%*
At 10 M/ml	*82%*	*96%*

Appendix V
Listing of Men With Non-Zero Sperm Concentration or Sperm Viability

Client Number	FSI Concentration	Nepal Concentration	Sperm Viability (%)
5021	6.5	7.3	59
5067	0.0	0.1	0
5072	0.0	0.0	100
5087	1.6	1.5	63
5138	0.0	0.0	100
5142	0.0	0.0	100
5144	3.7	2.1	.
5156	1.2	1.7	83
5221	0.0	0.0	100
5226	0.1	0.0	50
5275	0.0	0.0	100
5284	0.0	0.0	100
5292	0.5	0.3	62
5321	0.0	0.0	50
5336	0.0	0.0	50
5373	0.0	0.0	50
5379	2.6	2.0	68
6025	28.5	6.9	65
6032	1.3	1.3	40
6046	1.4	1.2	69
6082	39.7	13.2	67
6106	2.7	2.0	74
6123	43.3	11.9	65
6132	0.3	0.2	70
7030	.	0.2	60
7057	0.0	0.0	78
7093	12.6	4.4	82
7117	44.7	27.7	47
7128	2.5	1.9	77
7138	0.0	0.0	100
7139	0.2	0.0	60
7159	63.7	.	62
7243	100.5	97.8	79
7254	94.3	28.2	72
7270	2.3	2.4	70
7284	29.7	8.0	67
7285	77.9	29.9	82
8017	0.0	0.1	0
8053	0.0	0.1	0

Appendix V (continued)
Listing of Men With Non-Zero Sperm Concentration or Sperm Viability

Client Number	FSI Concentration	Nepal Concentration	Sperm Viability (%)
8064	0.0	0.0	100
8146	0.0	0.0	100
8212	0.0	0.0	100
8251	2.6	1.7	33
8303	0.0	0.1	0
8325	0.0	0.0	100
8346	0.0	0.1	0
8377	15.4	10.9	30
8433	4.6	4.8	28
8472	0.0	0.1	0
8478	0.0	0.1	0

Appendix VI
Design Effects for Estimates of Selected Statistics: Primary Analysis Population

Selected Statistics	Weighted Estimates	Design Effect
Prevalence of Persistent Sperm	3.3%	1.4
Prevalence of pregnancy 3 or more months after vasectomy	2.3%	2.0
Prevalence of any vasectomy failure (persistent sperm or pregnancy 3 or more months after vasectomy)	4.1%	1.5
Logarithm of odds ratio of persistent sperm and surgeon's routine excision of > 2 centimeters: (bivariable model)	-1.1	2.2