THE SOUTH CAROLINA PAPMOBILE PROGRAM: A SAS APPLICATION

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I. BACKGROUND

The South Carolina Papmobile project, a prospective study of cancer in women, has been in existence for more than three years. The study is being conducted by the Departments of Obstetrics and Gynecology and Biometry at the Medical University of South Carolina. Two full-time registered nurses travel in a specially equipped van from the Medical University in Charleston to communities throughout the eastern part of South Carolina. They conduct 85 to 90 half-day, one, two or three day clinics each year, obtaining over 3,000 Pap smears annually in these clinics.

The Papmobile Study is typical of the kinds of collaboration and consulting projects with which the faculty and students of the Department of Biometry are involved.

Data on each patient are recorded on a "Papmobile Code Sheet," a four page form developed at MUSC for this study. The first two pages, approximately twenty five questions, query the patient on historical information, such as her age, race, family income, any family history of cancer in females, current method of birth control. Volunteers at each clinic site help fill out the information. The nurses record their clinical findings of the breast, vulva, vagina, cervix, uterus, ovaries, rectum and indicate pathology on page three of the form. The physicians' follow-up results on referred patients comprise the fourth page. Copies of the code sheets are available from the authors.

The Papmobile team are attempting to examine the high risk women- the poor, the elderly and the sexually promiscuous. The Papmobile goes anywhere they are requested and a group of people can be scheduled for the examinations. Plant managers invite the Papmobile to park in their parking lot, and they excuse their female employees from their work for examination. Churches often request and publicize their presence to members and near-by residents. Colleges schedule Papmobile visits which are well received by students. The local American Cancer Society Chapters invite them to their community for a day and publicize their arrival.

The Papmobile schedule is usually filled two or three months in advance even though the Papmobile travels eleven months out of the year. In June, when most people seem to be on vacation, the van is serviced and the Papmobile personnel do their paperwork.

The South Carolina Papmobile is one of the few successful Papmobile programs in the United States. Dr. Paul Underwood, who heads the project, attributes the success to a concerted effort to make clear to the physicians in the various communities that the Medical University of South Carolina is not trying to compete with them. The Papmobile visits a community by invitation only and it seeks to provide examinations to women who are not being seen regularly by physicians. Women found to have abnormalities are not sent to MUSC, but are referred to local physicians. Each patient is asked whether she has a physician, and if she does, a report of the clinical findings is sent to him.

II. POPULATION CHARACTERISTICS

The 6749 records from the first two years of Papmobile operation reveal the following characteristics. Patients ages range from 14 years to 93 years with an average age of 43 ($\pm$ 16). Of those studied, 225 women, 3.4 percent, are younger than 20 years of age. There are 1839 patients, 27.3 percent, between the ages of 55 and 93 years. Approximately 130 women are at each year of age between 20 years and 54 years. This age distribution is consistent with the general population.

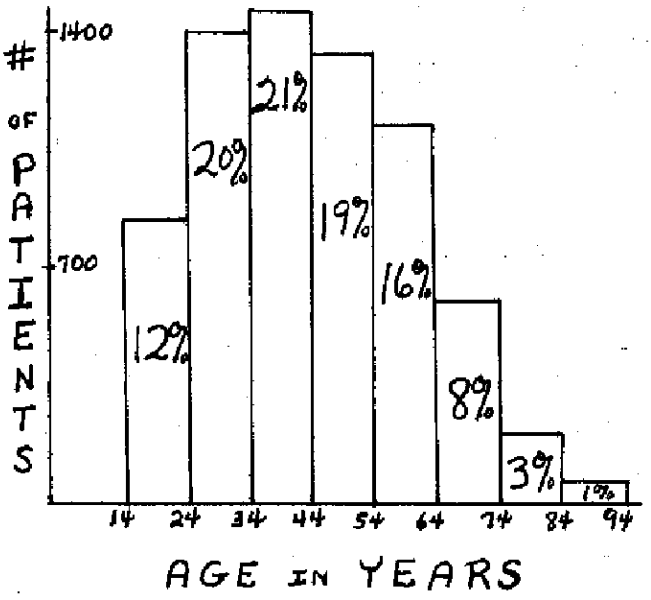

Diagram 1. Age Distribution

Among those attending the clinics are 2135 blacks, 31.6 percent of the total; 4585 whites, 68.0 percent; and 27 of other descent, 0.4 percent. See Diagram 2. This racial breakdown is approximately the racial mix of South Carolina as a whole.

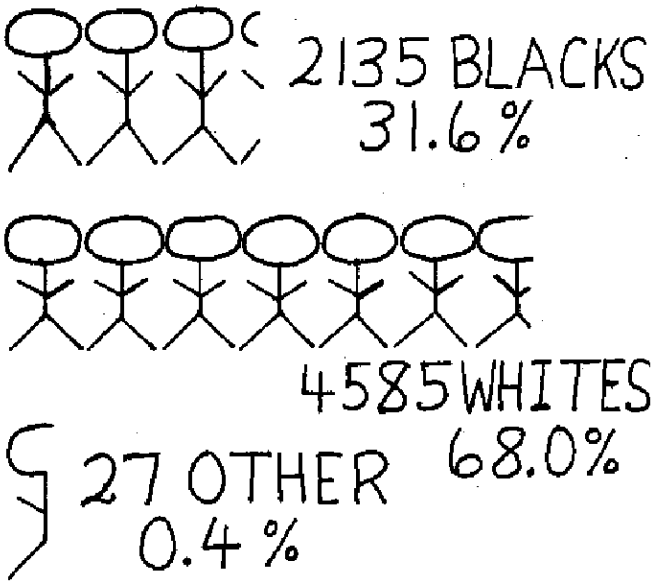

Diagram 2. Racial Composition

The majority of women who visit the Papmobile are married, 71.5 percent. Single women comprise 18.6 percent; widows, 12.8 percent; and divorced, 5.0 percent. See Diagram 3. Of the women who are or have been married, 76.3 percent record that they have been married once; 12.0 percent, twice; and 1.8 percent, either three or four times.

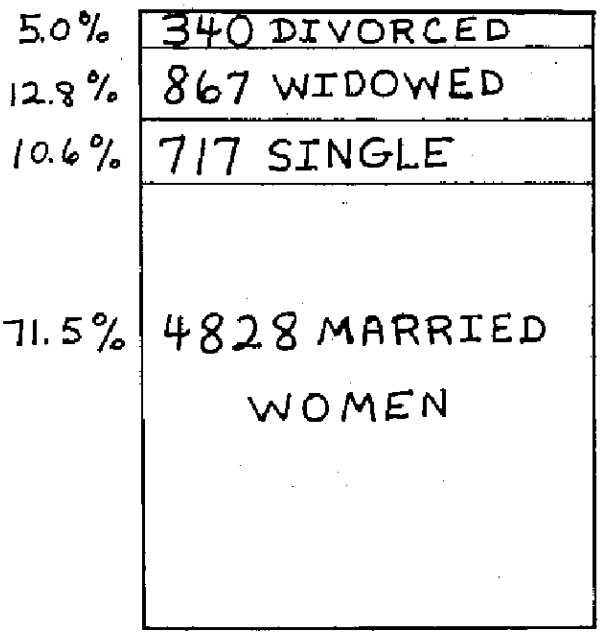

Diagram 3. Marital Status

Seventy percent of the women report their family income is less than 10,000 dollars. Of these, roughly thirty percent are from families having an income of less than 5,000 dollars. Only 1998 women, 29,8 percent, report a family income greater than 10,000 dollars. Hence, the Papmobile program appears to be reaching many poor women who possibly do not receive regular physical examinations. According to the literature, more abnormalities will be detected when Pap smears are given to an unscreened population than when given to a screened population. Interestingly, when asked if they had a physician, 6114, 90.7 percent, answer, "yes"; 628 or 9.3 percent say, "no."

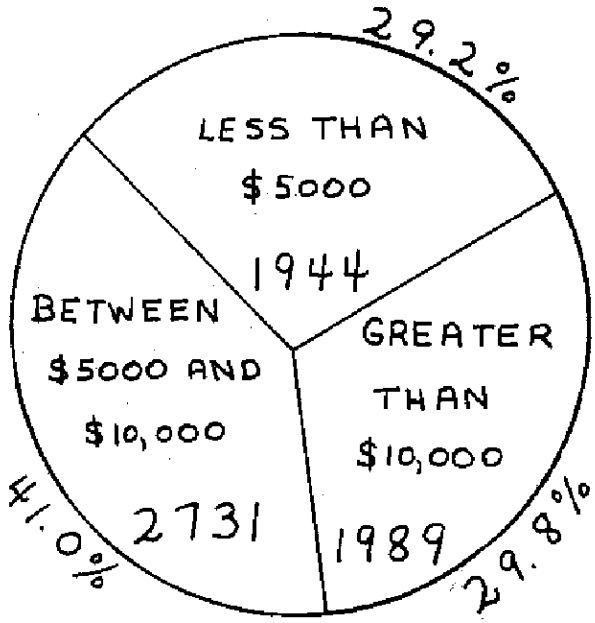

Diagram 4. Family Annual Income

III. INFORMATION FLOW

The structure of the information flow is shown in Diagram 6. The Papmobile nurses drive the van from the Medical University of South Carolina into the local communities to conduct the clinics. Volunteers fill out descriptive histories and the nurses record their findings for each patient on the Papmobile Code Sheet. Specimens are delivered to the lab, after which the results are sent to the Department of Obstetrics and Gynecology at MUSC. The Department of Biometry receives the completed examination forms from OB/GYN and the data are entered into a SAS data set.

Not only is the patient told of the examination findings, but her physician receives a report, if she indicates she has a physician. If any abnormalities are found, the patient is referred to her local physician for a second examination. After the physician sees the patient, he sends a follow-up report (fourth page of the Papmobile Code Sheet questionnaire) to the Papmobile study team in OB/GYN. This report becomes a part of the patient's record which is sent to Biometry.

FINDINGS \ FOLLOW UPS	BREAST	VULVA	VAGINA	CERVIX	UTURUS	LEFT OVARY	RIGHT OVARY
BREAST	**						
VULVA		**					
VAGINA			**				
CERVIX				**	**		
UTURUS				**	**		
OVARY					**	**	**

$\chi^2_{\alpha=.01}$

Diagram 5. Findings and Follow-Ups

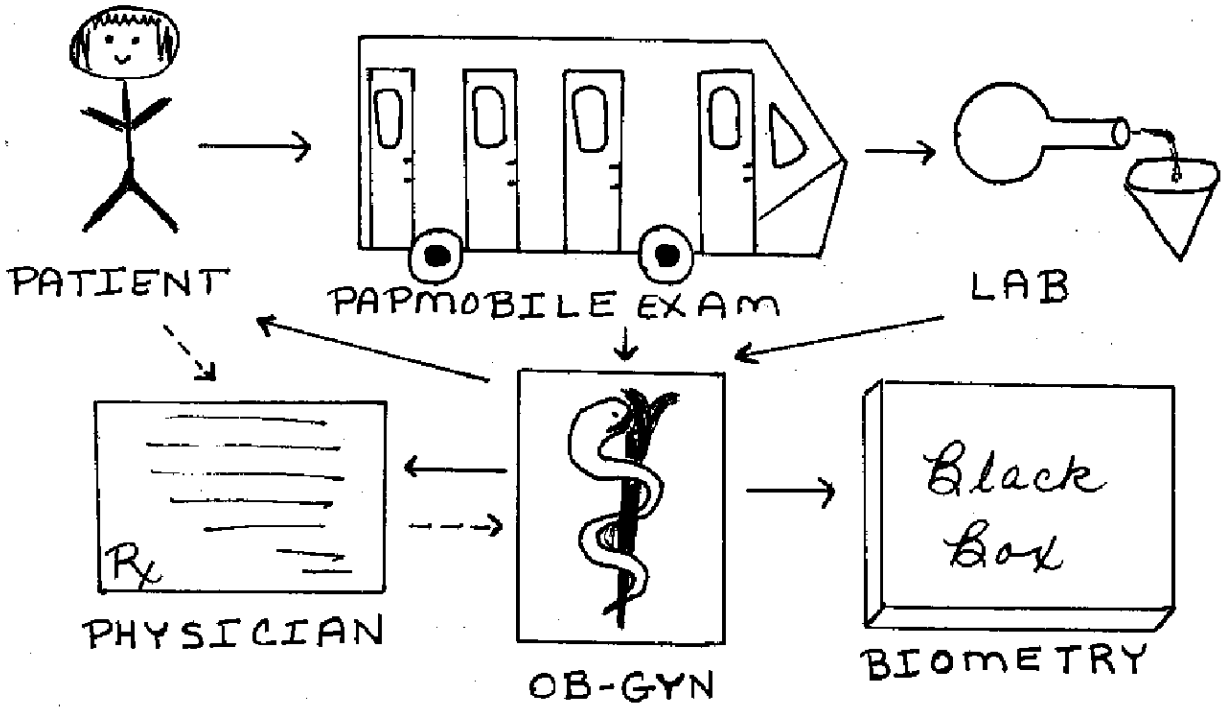

Diagram 6. Information Flow

IV. ANALYTIC SYSTEM

SAS-76 handles the data management needs of the study. The file structure of the data is simple, only a master file is needed with a single sort on new data prior to updating the file, as has been observed by other users. Corrections of detected errors from the edit program or the staff are done with relative ease with SAS. At the Medical University we operate under CMS, which means, at the present time, once a SAS job has been entered on a terminal, it must be released to the batch queue for processing. This is a disadvantage, but the time factor for this project is not a critical one and is outweighed by the flexibility and options available in SAS. A useful feature of the package is the ability to call BMDP and SPSS from inside a SAS job.

V. ANALYSES

Preliminary analyses are completed for the information collected by the Papmobile Study to date. Since the program is ongoing, the data base is ever increasing, and some periodic, regularly scheduled further analyses are planned. The Papmobile project team has hypothesized an association between the preliminary findings of the nurses and the follow-up diagnoses of the physicians. Indeed, this appears to be so. Chi square tests of the preliminary findings and follow-up data show significance at the .01 level in the areas of breast, vulva, vagina, cervix, uterus and ovaries. The findings shown in Diagram 5 are categorized as: 1) normal or 2) enough abnormality to require further examination; the follow-up data in the diagram are classified as: 1) no follow-up necessary, 2) benign disease or 3) malignant disease. The cervix classifications are divided into more specific categories.

The Pap reports returned to OB/GYN from the lab are classified into several different categories, as is the question pertaining to the Pap report on the Papmobile Code Sheet. The report can be negative or show minor atypia. The latter is of little concern to the patient as the cervix will most likely return to a negative state if a repeat Pap smear is done later. The report can show mild dysplasia or moderate dysplasia, neither of which causes undo concern as either, too, will probably return to a negative state on a repeated testing. However, severe dysplasia is a signal for careful monitoring of continued development as frequently it will become carcinoma. Suspicious cells also bear watching as these cells have characteristics different from those of normal cells, although they are unlike cancer cells. The final categories are the alarming ones: carcinoma in situ, adenocarcinoma cells and invasive squamous cell carcinoma.

The objective of the Papmobile project is the detection and prevention of cancer. Identifying women who have carcinoma and do not realize it, is the function of the Papmobile team. Of the first 6749 women examined by the program, 93 patients have had a non-negative Pap report. These women, along with those for whom abnormalities are found by examination, are referred to physicians for follow-up. See Diagram 7.

CERVIX FOLLOW-UP \ PAP REPORT	ϕ	1	2	3
NO FOLLOW-UP NECESSARY	6337	7	0	0
BENIGN CERVICAL DISEASE	117	39	15	3
MILD OR MODERATE DYSPLASIA	2	1	11	1
SEVERE DYSPLASIA CARCINOMA	1	1	5	10

Negative = ϕ
Minor atypia = 1
Mild dysplasia, Moderate dysplasia } = 2
Severe dysplasia, Suspicious, Carcinoma in situ, Adenocarcinoma cells, Invasive squamous cell carcinoma } = 3

Diagram 7. Pap Reports and Cervix Follow-Ups

The other objective of the study is to increase the understanding of the disease carcinoma. Using SAS programs such a PROC FREQ and BMDP programs available under SAS such as BMDP3F, we will search for associations between a patient's medical history and particular kinds of cancer. Obviously, one would like to be able to predict the risk at which a given patient finds herself, given her peculiar medical make-up. For example, it appears that women who have had hysterectomies suffer infrequently from abnormalities of the cervix. Is it valid to require these women to have a routine annual Pap smear? Diagram 8 shows the distribution of women receiving Pap smears in the Papmobile study, and women who have had an abnormal

Pap smear in the past five years. Of the 98 women in the study who have had hysterectomies, none has been treated for an abnormal Pap smear.

Have you ever been treated for an abnormal Pap smear?
00) None
01) Conization biopsy
02) Hysterectomy
04) Creams
08) Freezing
16) Other

PAP REPORT \ TREATMENT ABNORMAL PAP	NONE	HYSTERECTOMY	OTHER
NEGATIVE	6256	98	153
MINOR ATYPIA	74	0	5
MILD OR MODERATE DYSPLASIA	45	0	4
SEVERE DYSPLASIA-CARCINOMA	15	0	3

Diagram 8. Hysterectomies and Negative Pap Reports

A lesion on the cervix is irritated when brushed and bleeding may occur. Therefore, the presence of a lesion can result in bleeding with intercourse, bleeding after menopause or bleeding off and on all month. Likewise, lesions may be associated with abnormal menstrual periods. Hence, we might expect to find an association between abnormal menstrual periods and non-negative Pap smears. Using the 6749 patients in the present data base, a significant chi square is determined for this association. See Diagram 9.

PAP REPORT \ ABNORMAL MENSTRUAL PERIODS	NO	YES
NEGATIVE	5974 OBS. 5968.8 EXP.	174 OBS. 179.2 EXP.
MINOR ATYPIA	68 OBS. 70.9 EXP.	5 OBS. 2.1 EXP.
MILD OR MODERATE DYSPLASIA	38 OBS. 49.8 EXP.	3 OBS. 1.2 EXP.
SEVERE DYSPLASIA CARCINOMA	15 OBS. 15.5 EXP.	1 OBS. .5 EXP.

$\chi^2 = 7.585$ prob. = .0554

Diagram 9. Abnormal Menstrual Periods and Pap Reports

CERVIX FOLLOW-UP \ ABNORMAL MENSTRUAL PERIODS	NO	YES
NO FOLLOW-UP NECESSARY	5845 OBS. 5834.6 EXP.	164 OBS. 174.4 EXP.
BENIGN CERVICAL DISEASE	154 OBS. 162.2 EXP.	13 OBS. 4.8 EXP.
MILD OR MODERATE DYSPLASIA	11 OBS. 12.6 EXP.	2 OBS. .4 EXP.
SEVERE DYSPLASIA-CARCINOMA	13 OBS. 13.6 EXP.	1 OBS. .4 EXP.

$\chi^2 = 22.848$ prob. = 0.000

Diagram 10. Abnormal Menstrual Periods and Cervix Follow-Ups

One would also expect an association to exist between abnormal menstrual periods and the follow-up diagnoses on the cervix performed by physicians. This is indeed the case. There is a significant association between abnormal menstrual periods and cervix follow-ups at the .01 significance level. See Diagram 10.

Other associations considered in our study include those between such factors as age, race, marital status, family income, physician, age of onset of sexual activity, frequency of Pap smears, douching and follow-up diagnoses on the breast, vulva, vagina, cervix, uterus, ovaries, urinary tract and gastrointestinal tract. See Diagram 11. It is anticipated that the data base for the Papmobile program will increase by 3,000 entries per year. This large data base will permit us to identify the significance of weaker associations than those observed in our initial study.

VI. CONCLUSIONS

SAS provides an excellent data file management system. In conjunction with BMDP and SPSS, it offers access to a wide array of analytic software for analysis of data of this type.

FOLLOW-UP / PATIENT HISTORY	PAP REPORT	BREAST	VAGINA	CERVIX	UTERUS	OVARY
AGE	**	*	**		**	*
RACE	**		**	**		
MARITAL STATUS					**	
FAMILY INCOME			**			
PHYSICIAN			**			
AGE OF ONSET OF SEXUAL ACTIVITY		*	**			
FREQUENCY OF PAP SMEARS	*		**			*
ABNORMAL MENSTRUAL PERIODS			*	**	**	
DOUCHE	**		**	**		

χ^2

*: $\alpha = .05$
**: $\alpha = .01$

Diagram 11. Associations of Interest