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Potential Risk Factors in Air Force Women

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13. ABSTRACT (Maximum 200 Words) <p>Reproductive health outcomes and potential risk factors have not been studied among Active Duty Air Force (ADAF) women. Phase I describes natality and adverse outcome rates among women over a 20-year period (1975-1994) by age, race, rank, occupation, marital status, pay grade, geography, and AF Command. Accurate natality and adverse reproductive outcome rates indicate where improved health care planning is needed and provide a framework within which to interpret consequences of future deployment.</p> <p>Phase II case-control studies evaluate ADAF women from 1990-1998. Causal hypotheses evaluate possible effects of occupational and operational factors on risks of preterm delivery, pregnancy induced hypertension, and spontaneous abortion. The proposed cases (n=1,875) and controls (n=1,875) are ascertained using the Air Force Medical Support Agency (AFMSA) Standard Inpatient Record matched within 2 months of conception and the Air Force Base assignment. Exposure data recorded prior to pregnancy eliminates potential recall bias.</p> <p>This year we: 1) met human subject requirements, 2) revised the CATI, 3) maintained continuity with 82 Air Force Bases, 4) ascertained the cohort, 5) contact information, 6) phone numbers, 7) designed a tracking database, 8) sought new funding to cover the cost of obtaining informed consent, 9) designed tracking procedures, and 10) analysis.</p>			
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FOREWORD

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N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Dicina Echeverria
PI - Signature Date

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PROGRESS REPORT SUMMARY	CONTRACT NUMBER: DAMD17-96-C-6103 US Department of Defense, Army Materiel Command
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Diana Echeverria	Period Covered by this Report From 10/01/99 Through 9/30/00
TITLE OF PROJECT (Repeat title shown in item 1 on first page) An Investigation of Reproductive Health Outcomes and Potential Risk Factors in Air Force Women	

A. Introduction

Phase I: The longitudinal study is a descriptive assessment of reproductive experience among ADAF women providing background for Phase II hypothesis testing. The last 5 years of data will be used to model outcomes and project future natality and adverse pregnancy outcomes by geographic region and command.

1. Describe the natality and adverse reproductive outcome experience of ADAF women over 20 years from 1975 to 1994.
2. Describe differences in natality and adverse reproductive outcome rates for ADAF women by age, race, rank, occupation, marital status, pay grade, geographic region, and command.
3. Use 1990-1994 data to model future rates of natality and adverse reproductive outcomes for geographic region and Air Force Commands.

Phase II: Occupational exposures in the Air Force are associated with adverse pregnancy outcomes among ADAF women.

(formal hypothesis testing)

1. Are there associations between employment pertaining to AF occupations and preterm delivery, spontaneous abortion, or pregnancy induced hypertension?
2. Are there associations between chemical or physical exposures in AF occupations and preterm delivery, spontaneous abortions, or pregnancy induced hypertension?
3. Do the resultant odds ratios differ by age, race, smoking, alcohol consumption, rank, duration of service, occupation.

B. Results from Two Technical Reports

Herbold JR, Grayson JK, An Investigation of Reproductive Health Outcomes and Potential Risk Factors in Air Force Women, Phase 1: Technical Report 2-Active Duty Status and Adverse Reproductive Outcomes of Air Force Women, 1980-1994, US Army Medical Research and Materiel Command, September, 1998.

Herbold JR, Grayson JK, An Investigation of Reproductive Health Outcomes and Potential Risk Factors in Air Force Women, Phase 1: Technical Report 1-Natality Experience of Air Force Women, 1975-1994, US Army Medical Research and Materiel Command, December 1997.

Two abstracts have been presented and three publications are pending:

1. Baselining Air Force Working Women's Natality Rates, 1980-1994.

J. Herbold*, J. Grayson**, B. Bradshaw*, L. Sever***, D. Echeverria***, N. Heyer***, and B. Bell*

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ABSTRACTS OF THE 32nd ANNUAL MEETING
BALTIMORE, MARYLAND, JUNE 10-12, 1999

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ABSTRACTS

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¹This is the twenty-seventh year of publication of these proceedings. The *American Journal of Epidemiology* has published the Proceedings every year since 1974. The abstracts of papers presented at the Sixth Annual Meeting (1973) were published under the sponsorship of National Health and Welfare Canada.

* Presenter

** Truncated abstracts due to space limitations.

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EXTENT OF POSSIBLE BIAS FROM USING COMPENSATION CLAIMS: SILICOSIS AND LUNG CANCER. DF Goldsmith* (Department of Environmental and Occupational Health, George Washington University, Washington, DC 20037).

Background: Epidemiologists are warned not to use data from Workers' Compensation claims because of the possible biases introduced into studies, and this is particularly true regarding the link between silicosis and lung cancer. The present investigation was specifically designed to evaluate whether degree of bias could be measured by comparing the lung cancer risks from compensation claims versus medically derived cases of silicosis. Given the likelihood of bias, the hypothesis was that lung cancer risks would be higher among compensation-based sources. **Methods:** From the international published literature since 1980, the author compared 13 compensation based epidemiology studies and 23 studies using hospital records or disease registries as sources of silicosis study subjects. The mean and range of the lung cancer relative risk (RR) estimates were compared, adjusted for study power. **Results:** Only three studies showed RR=1.0 between silicosis and lung cancer, all from noncompensation sources of silicosis; the remainder demonstrated significantly ($p < 0.05$) elevated lung cancer RR. There was a range of RR from 1.36 to 6.94 for compensation claimants with an average risk of 2.03, while for medical cases the range was from 1.1 to 6.5 with an average RR of 2.44. **Conclusions:** These results suggest that the lung cancer risks derived from compensation sources of silicosis are not greater than from non-compensation data sources.**

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BASELINING AIR FORCE WORKING WOMEN'S NATALITY RATES, 1980-1994. J. Herbold,* J. Grayson, B. Bradshaw, L. Sever, D. Echeverria, N. Heyer, and B. Bell (Univ. of Texas-Houston Health Science Center School of Public Health, Houston, TX 77225).

Since 1975, Air Force policy has been to allow pregnant women to remain on active duty and to continue in the work force after the birth of their child. Further legislation in 1993 gave women in the military access to all occupational categories, including combat. This report provides the descriptive framework to understand better the relationship between fully employed work status (active duty) and patterns of natality. Natality among Air Force women is particularly relevant as women enter all career fields except for the very few restricted by law. We describe the natality experience of active duty Air Force women over a 15-year period, 1980 through 1994 and describe the differences in natality rates by age, race, and marital status. Natality rates were based on inpatient data records. The historical natality profile provides a framework within which to interpret the reproductive consequences of an increasing integration of women into a traditionally male workforce. Variability in natality rates across different demographic and occupational strata provide direction for targeted programs for occupational exposure protection, provision of health services, and personal implementation of lifestyle changes to protect the health of the mother and child. The baselines developed also provide the required background of descriptive information for analytic studies that evaluate hypotheses identified in the literature regarding the possible adverse occurrence of pre-term delivery, pregnancy induced hypertension, and spontaneous abortion among active duty Air Force women.**

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ISCHEMIC HEART DISEASE MORTALITY AMONG RUBBER MANUFACTURING WORKERS. Mary M. Prince,* Elizabeth M. Ward, Avima Ruder, Alberto Salvan, and Dennis R. Roberts (National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH 45226).

A retrospective cohort mortality study evaluated ischemic heart disease (IHD) risk among workers in the "rubber chemicals" manufacturing department in a chemical plant in Western New York. Mortality experience of workers employed at the study plant from 1946 through 1988 was followed through December 31, 1994. Mortality was compared to US population rates and to local county rates (Niagara County, 1960-1994) using the NIOSH lifetable analysis system. There were 708 workers with "definite exposure" to the rubber chemicals department, 291 workers with possible exposure to this department, and 750 who were considered "probably not exposed" to the rubber chemicals department. The standardized mortality ratio (SMR) for IHD among workers in the rubber chemicals department was 1.51 (95% confidence interval (CI) = 0.94-2.3) based on U.S. rates and 1.19 (CI = 0.75-1.8) based on Niagara County rates. Increased mortality from IHD was most pronounced at younger ages (< 50 , U.S. based SMR = 2.4; CI = 1.1-4.8; Niagara County based SMR = 1.93; CI = 0.9-3.8). Workers "probably not exposed" to the rubber chemicals department also had elevated IHD mortality in the < 50 age group (U.S. based SMR = 1.56; CI = 0.6-3.3; Niagara County based SMR = 1.36; CI = 0.54-2.9). The analysis found that IHD mortality among workers in the rubber chemicals department was elevated relative to IHD mortality in the U.S. population; some of this excess may be related to higher rates of IHD mortality in the county where the plant is located.**

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RECREATIONAL FIREARMS AND HEARING LOSS. D.M. Nondahl,* K.J. Cruickshanks, T.L. Wiley, R. Klein, B.E.K. Klein, and T.S. Tweed (University of Wisconsin, Madison, WI 53705).

Although military noise exposure has been shown to be associated with hearing loss, few studies have assessed the association between recreational firearm use and hearing loss. As part of a population-based study of hearing loss in adults (48-92 years of age; $n=3,753$) conducted in Beaver Dam, Wisconsin, self-reported firearm use during target practice and hunting were assessed by interview. Hearing loss was measured by pure tone audiometry. Few women were involved in gun-related activities, so our report is limited to findings in men ($n=1,538$). We defined a marked high frequency hearing loss (MHFHL) as the pure tone average of hearing thresholds at 4, 6 and 8 kHz > 60 decibels in the worse ear. After adjusting for age, occupational noise exposure, smoking, alcohol consumption, cardiovascular disease, education and head injury, men who had ever regularly engaged in target practice (15.6%) were more likely to have a MHFHL than those who had not (odds ratio (OR) = 1.71, 95% confidence interval (CI) = 1.23, 2.37). Relatively few men older than 65 years had regularly engaged in target practice or hunting within the past year. Among younger men, recent target practice and recent hunting were associated with an increased risk of having a MHFHL (target practice OR=2.93, 95% CI=1.59, 5.38; hunting OR = 1.53, 95% CI = 1.10, 2.13). Thirty-eight percent of recent target shooters never wore hearing protection while shooting. These results indicate that use of recreational firearms is associated with MHFHL in men. Target shooters should consider following recommendations for use of hearing protection.

**ABSTRACTS OF THE 32ND ANNUAL MEETING
OF THE SOCIETY FOR EPIDEMIOLOGIC RESEARCH
BALTIMORE, MARYLAND, JUNE 10-12, 1999**

SESSIONS:

- S1 **Poster Session I**
Spotlight Session #1
- S18 **Observational Studies and Controlled Trials: What Are We to Believe When the Results Are Discrepant?**
- S19 **Social Epidemiology: Measures of Risk**
- S20 **Assessment of Patient Outcomes**
- S21 **Environmental Threats to Male or Female Reproductive Health**
Spotlight Session #2
- S22 **Diet, Nutrition and Cancer**
- S23 **Race and Class Inequalities in Health**
- S24 **Epidemiologic Issues in Measurement of Quality of Health Care**
- S25 **Methodological Issues in Randomized Clinical Trials**
- S26 **Women's Reproductive Health: It's Risk Factors and It's Effects**
Spotlight Session #3
- S27 **Reducing the Population Burden Due To Cancer**
- S28 **Pregnancy Outcomes and Socioeconomic Inequalities**
- S28 **Running for Your Life: Measurement and Effects of Physical Activity**
- S29 **Gender, Ethnicity and Mental Health**
- S30 **Poster Session II**
Spotlight Session #4
- S48 **Molecular Epidemiology in Cancer Research**
- S49 **Cardiovascular Disease Prevention Research**
- S50 **Birthweight, Gestational Age and Fetal Growth: Optimal Methods of Analysis**
- S50 **Epidemiologic Assessment of Vaccine-Preventable Infectious Diseases**
- S51 **Community Characteristics and Inequalities in Health**
Spotlight Session #5
- S52 **Gene-Environment Interactions and Chronic Disease Outcomes**
- S53 **Effects of Physical Activity & Body Size on Breast Cancer**
- S54 **Infectious Agents in Cancer Etiology**
- S54 **Pharmacoepidemiology**
- S55 **Statistical Methods in Epidemiology**
Spotlight Session #6
- S56 **Benefits and Risks of Hormone Replacement Therapy**
- S57 **Biological Effects of Low Level Exposures**
- S58 **Environment and Congenital Malformations**
- S59 **Epidemiology of Smoking Behavior and Control of Tobacco Consumption**
- S60 **Poster Session III**
- S77 **Latebreaker Session**

2. Abstract and Paper #15616

Disparity Between Working Women's Natality Rates and Vital Statistics - Implications for Occupational Hazard Assessment of Adverse Reproductive Outcomes

John R. Herbold, DVM,MPH,PhD¹, J. Kevin Grayson, DVM,MPH,PHD², Benjamin S. Bradshaw, PhD¹, B. Sue Bell, PhD¹, Diana Echeverria, PhD³, and Nicholas Heyer, PhD³. (1) Border Campus, Univ. of Texas School of Public Health, Mail Code 7976, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900, fax: 2105675942, (2) United States Air Force, (3) Battelle Memorial Institute

This study describes the natality experience of active duty Air Force women and compares this experience with US vital statistics over a 15-year period. Maternal occupation has been reported to have adverse effects on pregnancy outcomes and some investigators have described military pregnancies as "high risk". However, without baselining the unique natality patterns of this working population, it is impossible to accurately evaluate whether adverse reproductive outcomes are high, low, and/or confounded by age, race, and marital status. Summary demographic measures of fertility are provided for comparison to those for women in the general United States population. The trends are the same in both the white and black Air Force population and, except for the early 1980's, black and white women had virtually identical fertility. While period fertility rates of the general US female population on average are higher than those of women in the Air Force, Air Force women have had consistently higher fertility rates than employed women in the United States labor force. This finding is among the more surprising results of this study. Trends over time indicate that many Air Force women found no conflict between active duty status and raising a family. As the proportion of women in uniform increases and restrictions against employment in potentially hazardous occupations are relaxed, it is essential that studies of occupational risks in the workplace are not biased by an incomplete understanding of the demographic characteristics of the women in a particular work setting.

3. Analysis of Phase I Data

Revised Natality Analyses

Table 1 presents demographic characteristics for mothers who had a live birth among active duty AF women from 1980 to 1994. Table 2 presents the distribution of women in the AF for the years between 1980 to 1994. The number of live births is based on the data maintained by the Standard Inpatient Data Record and serves as our numerator data. The distribution of women in the AF is based on data maintained by the DMDC and serves as our denominator data. This AF population is not a sample. On the contrary, the population is the entire universe of live births among active duty AF women. Therefore analytic models are not prediction models. Rather the models could uniquely identify statistically significant determinants of the number of live births/1,000 women based on relationships between the set of demographic characteristics described above.

As with any data set, there are also known limitations for this data set that hamper interpretation of analyses. The study team is still waiting for individual denominator data to reanalyze the data for all factors simultaneously. At this point the information in Table 2 is overly aggregated and restricts examination of multiple factors in one model. One can examine age by marital status, age by race, and age by marital status, but not race by marital status. Multivariate models that include occupation, major command, and geographic location are even more limited in relation

Distribution of Live Births Among Active Duty AF Women by Calendar Year and Mother's Characteristics															
Year	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994
Total	4375	5116	5583	5319	5138	5229	5274	5705	5532	5483	5472	5220	4876	4615	4138
MARITAL STATUS															
Married	3297	3816	4080	3986	3868	3901	4002	4217	3968	4459	4453	4277	3702	3497	3148
Unmarried	544	621	701	586	594	666	640	848	865	997	1015	939	777	739	648
Missing	534	679	802	747	676	662	632	640	699	27	4	4	397	379	342
AGE															
Less than 20	329	416	334	202	176	154	174	212	212	215	188	141	147	216	175
20-24	2608	2846	3160	2961	2620	2525	2338	2534	2439	2416	2350	2189	1969	1955	1735
25-29	1228	1529	1672	1630	1745	1829	1993	2066	1931	1861	1900	1796	1622	1474	1272
30-34	181	302	373	476	532	614	657	747	779	779	814	860	858	724	672
35-39	24	22	43	45	60	103	107	133	160	198	208	214	264	233	253
40-44	5	0	1	5	4	4	4	12	11	14	11	19	16	11	31
45 and up	0	1	0	0	1	0	1	1	0	0	1	1	0	2	0
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RANK															
Enlisted	4078	4702	5095	4789	4552	4519	4644	5060	4899	4583	4525	4273	4006	3861	3463
Officer	296	414	488	529	555	573	623	643	632	630	633	678	670	594	578
Missing	1	0	0	1	31	137	7	2	1	270	314	269	200	160	97
RACE															
White	3501	3989	4399	4178	3935	4007	3990	4258	4172	4081	4059	3871	3644	3460	3052
Black	785	1005	1046	974	1058	1075	1104	1271	1184	1182	1189	1099	1004	905	788
Other	89	122	138	167	144	147	178	169	166	217	222	244	219	248	296
Missing	0	0	0	0	1	0	2	7	10	3	2	6	9	2	2
MAJCOM															
Logistics	341	381	390	408	432	414	401	379	392	374	396	388	357	370	389
Operations	2828	3288	3552	3596	3474	3373	3358	3738	3472	3485	3459	3305	3112	2825	2077
Training	365	427	495	460	420	465	526	590	576	565	500	576	503	562	507
Other	288	318	339	97	92	85	118	134	118	141	124	131	111	70	424
Missing	553	702	807	758	720	892	871	864	974	928	993	820	793	788	741
REGION															
CONUS	3772	4346	4696	4477	4364	4263	4346	4779	4530	4730	4686	4493	4011	3803	3376
USAFE	42	52	47	47	41	61	60	74	40	55	34	118	176	158	147
PACAF	28	37	38	45	23	33	26	11	29	20	51	41	88	106	94
Missing	533	681	802	750	710	872	842	841	933	678	701	568	601	548	521

Table 2 Distribution of All ADAF Women by Calendar Year and Characteristics

Year	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994
Total	61114	63732	65029	65845	66976	70552	74295	76003	75124	76244	73476	71335	67140	66054	66318
MARITAL STATUS															
Married	28347	31133	32642	33506	33603	34292	35916	37120	37492	38858	38479	38476	36391	36710	37023
Unmarried	32717	32559	32317	32327	33369	36256	38375	38883	37602	37190	34971	32853	30747	29264	29195
Missing	50	40	70	12	4	4	4	0	30	196	26	6	2	80	100
AGE															
Less than 20	8001	6927	5458	4572	4508	5811	6694	6567	5784	5964	4919	4087	4631	4442	2504
20-24	29605	30273	29932	28994	27642	27210	27467	27192	25819	26146	22852	21500	19962	19610	20351
25-29	17121	18563	19637	20472	21036	21607	22148	22184	21625	20462	19745	18268	16188	15484	15867
30-34	4606	5886	7460	8876	10185	11403	12351	12992	13319	13105	13901	13857	12228	11783	11894
35-39	930	1236	1629	2090	2745	3534	4448	5585	6700	7816	8917	9749	9603	9475	9675
40-44	501	506	536	571	592	722	925	1203	1498	2031	2690	3309	3830	4262	4786
45 and up	250	261	237	246	260	257	254	280	319	328	400	553	694	838	1051
Missing	100	80	140	24	8	8	8	0	60	392	52	12	4	160	200
RANK															
Enlisted	52273	54297	54759	55128	55795	58605	61779	63300	62237	62616	60235	58189	54765	53838	54094
Officer	8791	9395	10200	10705	11177	11943	12512	12703	12857	13432	13215	13140	12373	12136	12124
Missing	50	40	70	12	4	4	4	0	30	196	26	6	2	80	100
RACE															
White	48734	50479	50767	51012	51283	53428	55686	56627	55715	56828	54141	52571	49623	48610	48640
Black	10499	11308	12242	12798	13522	14680	15832	16378	16337	15959	16138	15587	14471	14243	14310
Other	1831	1905	1950	2023	2167	2440	2773	2998	3042	3261	3171	3171	3044	3121	3268
Missing	50	40	70	12	4	4	4	0	30	196	26	6	2	80	100
MAJCOM															
Logistics	4373	4535	4913	5256	5596	5911	6072	4980	5008	5257	5256	5251	5236	5917	6204
Operations	37969	41017	42828	43995	43933	45250	48450	49667	49912	50513	51155	51117	44502	41102	33274
Training	11720	10771	10452	10048	10353	11970	11729	11675	10548	11049	10177	10324	10900	12192	12855
Other	7097	6738	6833	6609	7198	7538	8156	9782	9713	9949	6985	4897	6647	6864	12805
Missing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
REGION															
CONUS	52694	53699	55126	55882	57112	59926	62975	64074	63229	64636	59413	58712	55161	54906	55203
USAFE	5782	6462	6926	7103	7113	7673	8104	8590	8498	8461	9079	8030	7107	6032	4836
PACAF	2683	2900	2974	2923	2855	3070	3328	3440	3454	3671	5081	4847	5017	5137	5099

to these factors because individual denominator data has not been provided to the study team. Therefore, recognize that the relative weights of coefficients are attributable to artificial stability in the data.

Given these limitations, the relationship between natality rates (# of live births/1,000 women) and age, race, marital status, and rank (the first set of categories presented in Tables 1-2 above) is presented in a descriptive manner using the two models below. In the first model, we explain 81% of the variance using age, race, rank, and year. The results clearly indicate that age is the most important factor, followed by rank, year, and race. The series of graphs following the ANOVA illustrate these relationships. Natality rates should and do decrease with age. Natality rates are higher among enlisted personnel. Natality rates also have been gradually rising in the AF but as of 1992 they appear to be dropping. For the most part the differences in rates between Whites and minorities is very small where natality rates for Blacks are slightly lower than rates for Whites after 1992. The statistical significance of interaction terms is expected and is influenced by reliance on aggregated data so interpretation of these coefficients is problematic. However, broad trends in rates are clear and consistent within categories.

ANOVA1 : race, rank, and age are Categorical, YEAR2 is Continuous
denominators: year, race, age, and officer-enlisted status

Number of obs = 1037989 R-squared = 0.81
 Root MSE = 13.2263 Adj R-squared = 0.81

Source	Partial SS	df	MS	F	Prob > F
Model	767596734	33	23260507.1	132965.64	0.0000
year2	1411666.77	1	1411666.77	8069.61	0.0000
age	128162291	6	21360381.9	122103.82	0.0000
race	281970.217	2	140985.108	805.92	0.0000
offenlis	9074436.91	1	9074436.91	51872.83	0.0000
age*race	5424646.77	12	452053.898	2584.11	0.0000
race*offenlis	1120276.78	2	560138.391	3201.96	0.0000
race*year2	1993098.77	2	996549.386	5696.64	0.0000
offenlis*year2	12114827.7	1	12114827.7	69252.82	0.0000
age*year2	6374523.07	6	1062420.51	6073.19	0.0000
Residual	1815759291037955	174	936224		
Total	9491726621037988	914	435102		

Source	SS	df	MS
Model	767596734	33	23260507.1
Residual	1815759291037955	174	936224
Total	9491726621037988	914	435102

Number of obs = 1037989
 F(33,1037955) = .
 Prob > F = 0.00
 R-squared = 0.81
Adj R-squared = 0.81
 Root MSE = 13.23

		Coef.	Std. Err.	t	P> t	[95% Conf. Interval]	
Rate		94.964	.0247621	3835.064	0.000	94.915	95.012
year2		-.587	.005354	-109.734	0.000	-.598	-.577
age							
	1	-57.123	.0587823	-971.782	0.000	-57.238	-57.008
	3	-3.593	.0382765	-93.883	0.000	-3.668	-3.518
	4	-32.414	.0471995	-686.756	0.000	-32.507	-32.322
	5	-60.917	.0684012	-890.586	0.000	-61.051	-60.783
	6	-75.372	.1172994	-642.562	0.000	-75.602	-75.142
	7	-77.030	.2015892	-382.115	0.000	-77.425	-76.635
race							
	2	-1.676	.0548427	-30.564	0.000	-1.783	-1.568
	3	-16.234	.109553	-148.193	0.000	-16.449	-16.020
offenlis							
	2	-18.757	.0412384	-454.848	0.000	-18.838	-18.676
age*race							
	1 2	11.669	.1340751	87.038	0.000	11.406	11.932
	1 3	9.127	.2653432	34.400	0.000	8.607	9.647
	3 2	-2.379	.0814803	-29.205	0.000	-2.539	-2.219
	3 3	7.584	.1687919	44.936	0.000	7.253	7.915
	4 2	-6.651	.0974395	-68.265	0.000	-6.842	-6.460
	4 3	20.702	.2117088	97.788	0.000	20.287	21.117
	5 2	-6.677	.1276295	-52.321	0.000	-6.927	-6.427
	5 3	15.025	.2824692	53.192	0.000	14.471	15.578
	6 2	-3.562	.2181562	-16.332	0.000	-3.990	-3.135
	6 3	17.690	.4494591	39.360	0.000	16.809	18.571
	7 2	-5.373	.5673689	-9.471	0.000	-6.485	-4.261
	7 3	15.874	.7887769	20.125	0.000	14.328	17.420
race*offenlis							
	2 2	8.334	.1090481	76.426	0.000	8.120	8.547
	3 2	-3.589	.2013298	-17.827	0.000	-3.983	-3.194
race*year2							
	2	-.098	.0081698	-12.011	0.000	-.114	-.082
	3	1.728	.016567	104.316	0.000	1.695	1.760
offenlis*year2							
	2	2.361	.0089729	263.159	0.000	2.343	2.378
age*year2							
	1	-.245	.0122299	-20.034	0.000	-.268	-.221
	3	.990	.0079367	124.855	0.000	.975	1.006
	4	.733	.0099988	73.347	0.000	.713	.752
	5	-.637	.0144722	-44.055	0.000	-.665	-.609
	6	-1.568	.0233671	-67.118	0.000	-1.614	-1.522
	7	-1.644	.039195	-41.946	0.000	-1.720	-1.567

ANOVA2 - 08/07/00

MARITAL STATUS, RANK & AGE are Categorical YEAR2 is Continuous
 denominators: year, marital status, age, and officer-enlisted status

Number of obs = 1037989 R-squared = 0.96

Root MSE = 11.9617 Adj R-squared = 0.96

Source	Partial SS	df	MS	F	Prob > F
Model	3.1529e+09	16	197059018	1377249.48	0.0000
year2	12512750.5	1	12512750.5	87451.87	0.0000
age	594334816	6	99055802.7	692303.02	0.0000
married	262279087	1	262279087	1833073.87	0.0000
offenlis	645472.877	1	645472.877	4511.22	0.0000
age*married	372795180	6	62132530.0	434245.52	0.0000
married*offenlis	31610629.8	1	31610629.8	220927.33	0.0000
Residual	1485146631037972		143.08157		

Total | 3.3015e+091037988 3180.63306

Source	SS	df	MS
Model	3.1529e+09	16	197059018
Residual	1485146631037972	143.08157	
Total	3.3015e+091037988	3180.63306	

Number of obs = 1037989
 F(16,1037972) = .
 Prob > F = 0.00
 R-squared = 0.95
 Adj R-squared = 0.95
 Root MSE = 11.96

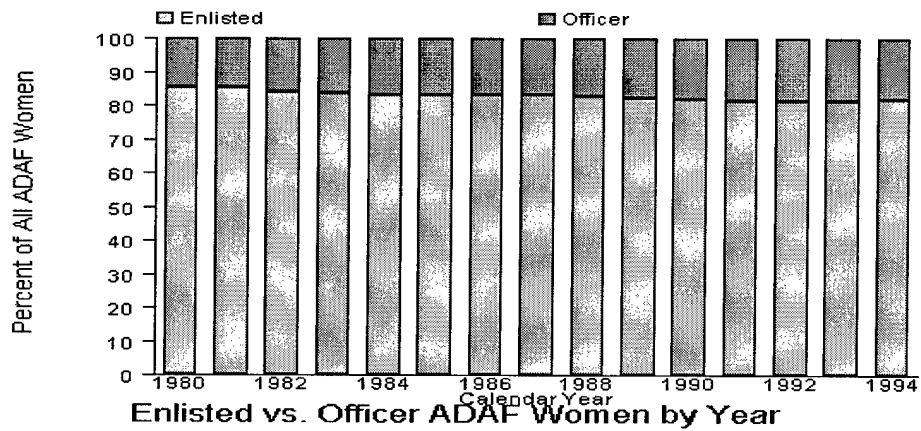
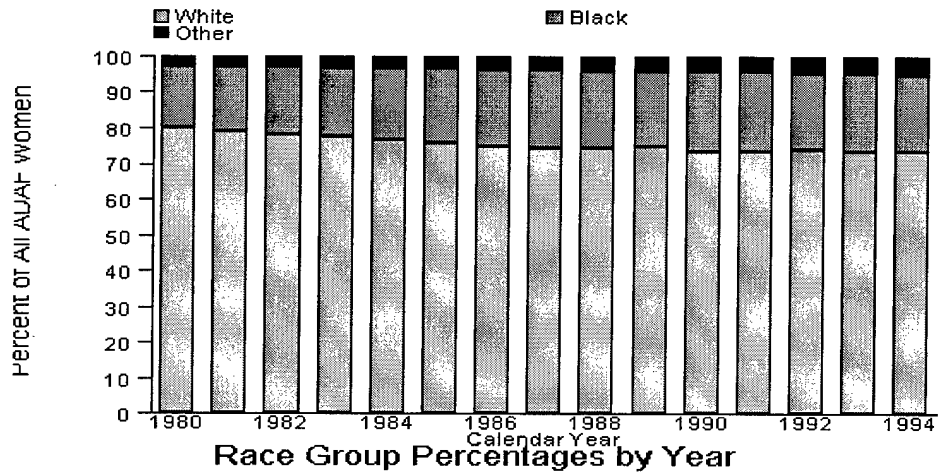
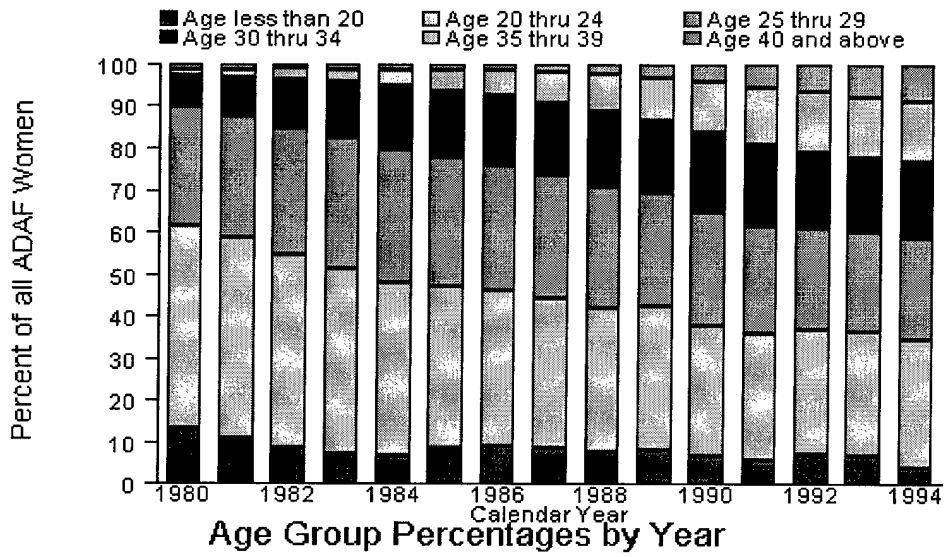
	Coef.	Std. Err.	t	P> t	[95% Conf. Intervall]	
rate	154.404	.0292557	5277.750	0.000	154.346	154.461
year2	.853	.0028875	295.723	0.000	.848	.859
age						
1	33.660	.1203156	279.770	0.000	33.424	33.896
3	-39.018	.0415393	-939.327	0.000	-39.100	-38.937
4	-85.935	.0482576	-1780.765	0.000	-86.030	-85.840
5	-128.747	.0612425	-2102.247	0.000	-128.867	-128.626
6	-156.449	.100147	-1562.194	0.000	-156.645	-156.252
7	-165.193	.2154338	-766.796	0.000	-165.616	-164.771
married						
2	-123.042	.0391191	-3145.325	0.000	-123.119	-122.965
offenlis						
2	13.477	.0466026	289.206	0.000	13.386	13.569
age*married						
1 2	-50.060	.1310942	-381.865	0.000	-50.317	-49.803
3 2	34.091	.0603977	564.445	0.000	33.972	34.209
4 2	72.126	.0745916	966.948	0.000	71.980	72.272
5 2	106.956	.0968393	1104.474	0.000	106.766	107.146
6 2	134.143	.1540551	870.750	0.000	133.841	134.445
7 2	147.363	.3096456	475.909	0.000	146.756	147.969
married*offenlis						
2 2	-31.455	.0669231	-470.029	0.000	-31.586	-31.324

The second ANOVA model differs from the first model in that the first excludes marital status and the second model excludes race. In the second model one can explain 95% of the variance by marital status, followed by age, rank, and year. Clearly age, rank, and year measure time which are collinear so it is expected that year will be left with an artificially smaller coefficient than what it should be. However, until we receive individual denominator data, correcting for collinearity by removing overlapping sums of squares to isolate potential confounding or interaction and even estimating the denominators for missing cells is unwarranted. We prefer to wait and reanalyze the data with proper sources of variance. Further, these models do not include occupation or operational variables such as job title, pay grade, major command, or location. These models also will be generated upon receipt of the aggregate data.

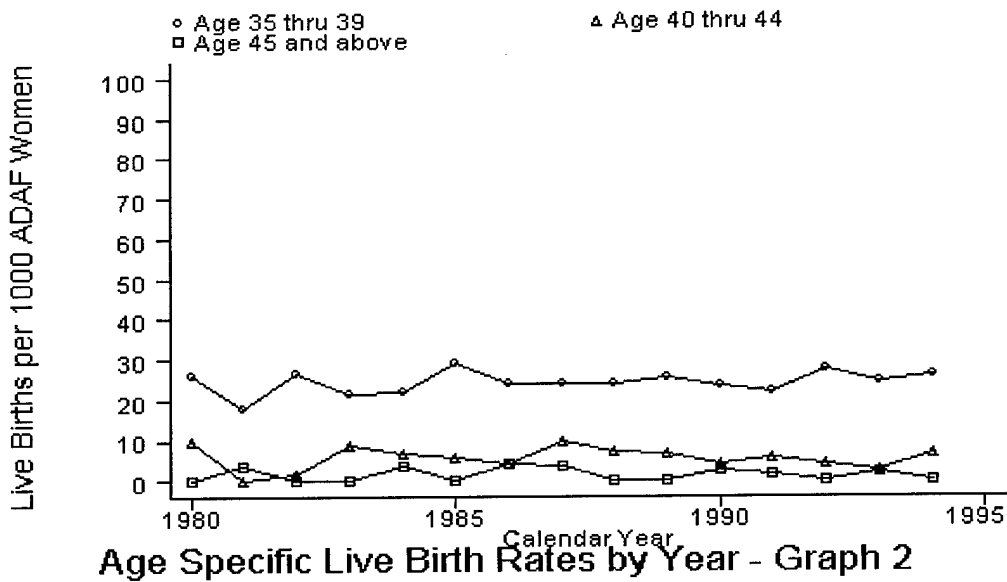
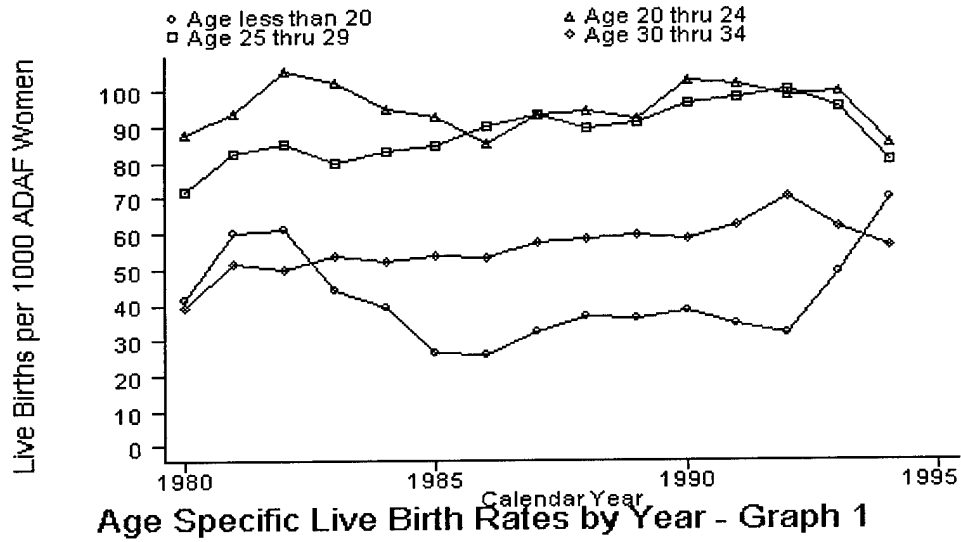
Overall, the strength of the current analyses is that it is easy to find statistically significant factors. The weakness is that one can not use the relative weight of coefficients against each other as true indicators of the magnitude of the predictor.

The findings suggest that age and marital status are likely the most meaningful predictors of natality. The analyses of race is at this point limited because race and marital status are not in the same model. The results do suggest that minor differences in race alter rates where minorities have smaller natality rates indicating they benefit by being in the AF environment. However, these estimates of coefficients are descriptive and must be interpreted in light of the interaction terms which again rely on overly aggregated data. The primary analytic problem is the unfortunate aggregation of race which can be overcome by the use of individual denominator data. It would serve the AF well to provide us with the data in order to prove that AF policies are appropriate and supportive of minority women.

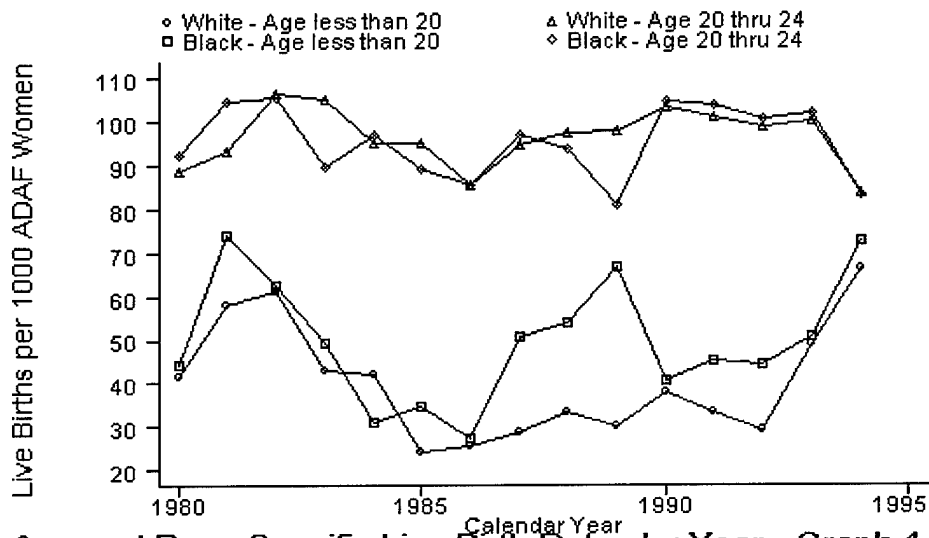
The three bar graphs below present the distribution of age, rank, and minorities included in the analyses of variance. The results indicate AF women are getting older and the proportion of officers and minorities is growing - likely the result of high re-enlistment rates and AF benefits.



The age specific rates and race specific rates presented in the series of graphs below basically indicate a gradual rise in natality rate until the year of 1992. At that point in time, the rates significantly decline in 1993 and 1994 where Black rates are lower than that of Whites – particularly among the older age groups.

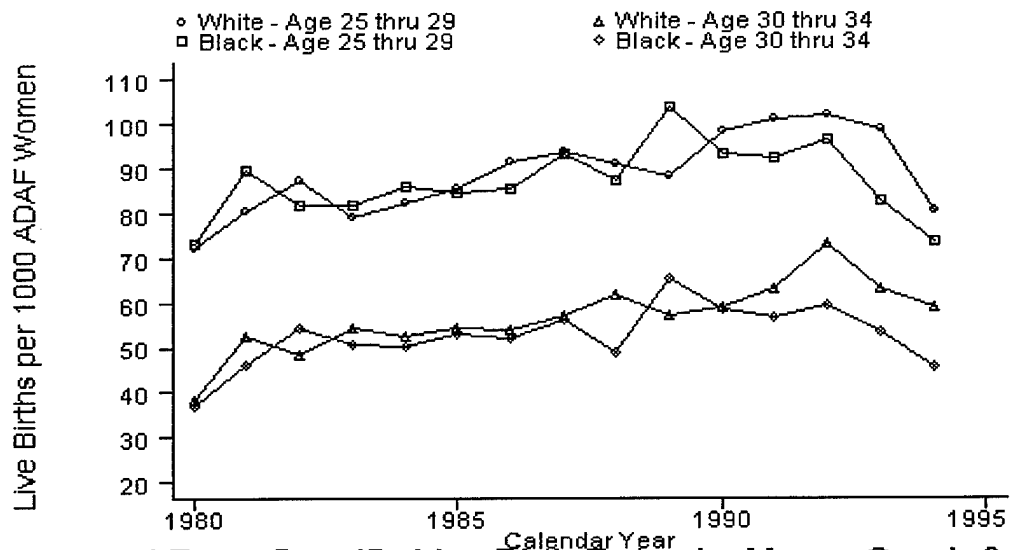


Age and race specific natality rates are expectantly higher among the 20 to 24 year olds.



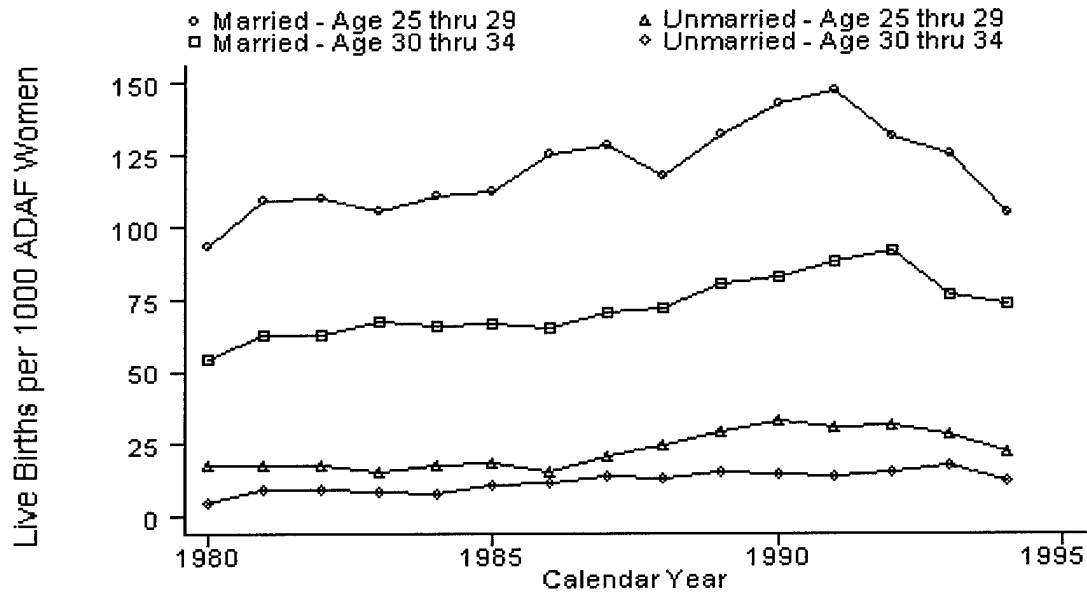
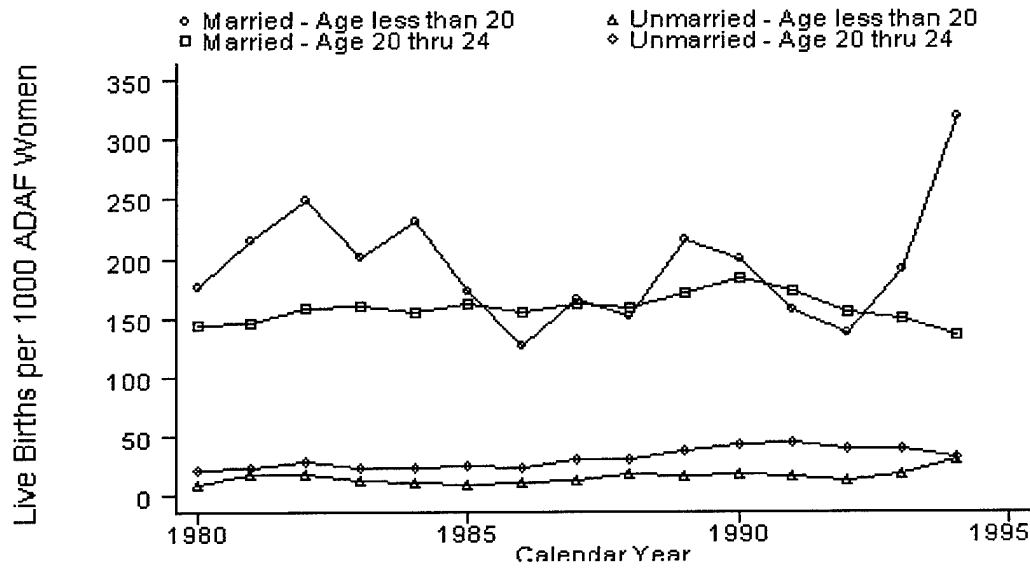
Age and Race Specific Live Birth Rates by Year - Graph 1

Similar to trends in the other graphs, there is an increase in rates for most age groups until 1992 (ignore the youngest age group under 20 years old where instability due to small numbers accounts for the observed variation in rates).

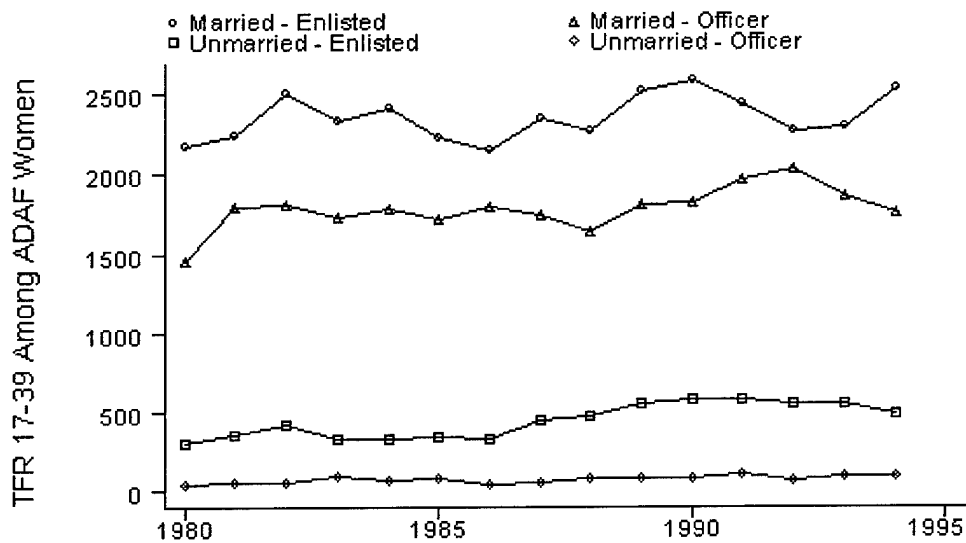


Age and Race Specific Live Birth Rates by Year - Graph 2

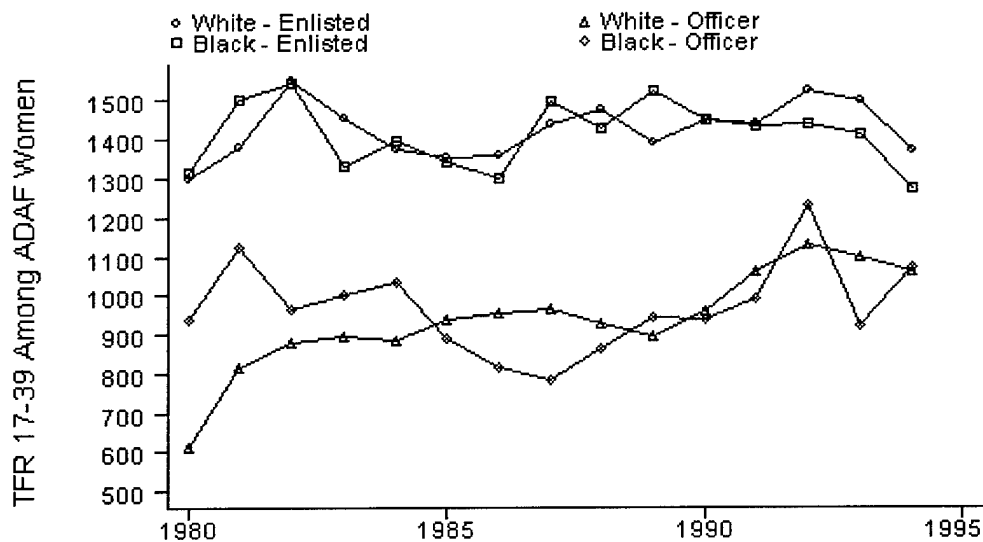
Marital Status and Age Specific Live Birth Rates by Year



Nativity rates are greater among married women. Though far less pronounced, there also is a detectable rise in natality among unmarried women.



Marital Status and Rank by Year for Total Fertility Rates



Race and Rank by Year for Total Fertility Rates

The Total Fertility Rate (TFR) is a traditional measure of natality used in the civilian literature which we consider less meaningful than an age-specific rate. A comparison of the two sets of TFR graphs illustrates the relative importance of marital status and rank over race. Given that rates for Whites and rates for minorities track closely together, we are confident that both groups are impacted equally by AF policies. Further, the rates for Blacks appear slightly lower than the rates for Whites in the last several years indicating that Blacks may benefit from employment in the AF. Note that the rates for Black officers are more variable indicating greater instability in ratios due to the influence of small numbers in the numerator and denominator.

A comprehensive analyses of these factors would assist the AF and we look forward to providing accurate and more meaningful coefficients for determinants of these rates using individual denominator values.

In addition to describing AF natality, we also propose to publish manuscripts describing a comparison between AF and civilian natality rates. This step also can not be accomplished without access to individual denominator data and civilian hospitalization data. We have obtained tapes for US hospitalizations in the civilian sector but are still waiting for the individual denominator data.

Upon receipt of the denominator data we propose to:

- reanalyze AF natality with all factors simultaneously
- analyze AF natality for fliers
- analyze AF natality rates vs. civilian rates
- analyze AF adverse outcomes with all factors simultaneously.

C. Phase II Case/Control Study

The Phase II study formally started in October 1, 1998. Over the year of 1999 all preparatory stages were completed and the mailing and interviews start February 15, 2000. To achieve this stage we had to complete nine critical steps: 1) meet human subject requirements, 2) conduct a pilot study, 3) revise the CATI, 4) ascertain permission from 82 Air Force Bases and minor installations, 5) ascertain the final cohort, 6) ascertain addresses, 7) ascertain phone numbers, 8) design the database, and 9) data collection. These activities were summarized in the Annual Report submitted in 1999.

Over the year of 2000, we have continued to conduct the same scope of work where the largest obstacle has been obtaining a signed human consent. As predicted, the labor and effort of the process has cost the project a disproportionate amount of money which otherwise would have been used to conduct the CATI and the analyses. The IRB requirement was never proposed in the original statement of work and has forced the team to reduce the scope of research as described below.

A summary of our activities in 2000 is described in this section. Our work is represented by ten basic topics. They are to: 1) meet human subject requirements, 2) revise the CATI to include SES questions, 3) maintain continuity and renewed permission to collect data on 82 Air Force Bases and minor installations, 4) ascertain the new cohort, 5) ascertain contact information, 6) ascertain phone numbers, 7) design a tracking database, 8) seek new funding to cover the cost of obtaining informed consent, 9) design a tracing and tracking procedure, and 10) data collection and analysis of the case/control study.

1. Meet Human Subject Requirements

In an effort to remove the foreseen consequences of the high cost of obtaining a consent form, we stopped data collection in the months of May, June, and July in order to request a new full human subject's review of the project by Travis Air Force IRB in June, July, and August. At that time we requested the Travis AF IRB review several options. The text of what we submitted to the IRB is reproduced in the space bordered in gray below.

This is a request for modifications in the above referenced study.

Modification #1: Enrollment and Consent

A) Consent Procedures

The enrollment procedure previously approved by Travis AFB IRB has proven to be ineffective and expensive.

Problems are:

1. Very low response rate.

The rate of response to our mailed invitation to potential subjects is extremely low – approximately 10%. We have mailed invitations to participate to 7,950 women and have received back 564 consent forms and have interviewed approximately 300, with an additional 50 or so women with signed consent forms to be interviewed. This low rate is unprecedented in any other study we have conducted.

2. Poor contact with subjects through the mailing.

We are concerned that the low response rate may be associated with low levels of successful delivery of the packets. Air Force women move frequently (10% every three months) and updated addresses and phone numbers are not clear. For example, when we mail letters to the women in the AF we are not sure if the mail room knows where to forward the letter.

A small study to evaluate delivery rates was conducted with 50 active duty Air Force women, and 50 women who have left the Air Force. A "return receipt requested" letter, which requires a signature, was sent to these 100 women. Active duty women had their letters sent to their AFB. All these letters were signed and the receipt returned. However, the receipt had been signed not by the woman, but by some Air Force clerk. It was thus impossible to track whether or not the woman actually received the letter. Among the 50 civilian women, approximately 30 had signed receipts returned, and the post office returned 6 for the wrong address. Upon follow-up, we determined 30% had moved on follow-up, again making a clear interpretation of mailing efficiency difficult.

3. High level of effort required to reach each subject by phone.

Our post-mailing follow-up effort has required approximately 10 phone calls per subject to actually speak to the woman, or to determine we have a bad phone number. With this level of difficulty in reaching subjects by phone, it is important to collect as much information as possible with each contact.

The current protocol requires us to use the first contact to establish whether or not the subject is interested, and to confirm address and phone number information. The consent package is then re-sent to the subject. If a consent form is received, a second call is made to schedule and/or conduct the interview. However, if the consent form is not received, an additional follow-up call is required.

Our experience is that interest levels are high, and very few women who are contacted actually refuse to participate. However, return rates for re-sent consent forms are low. This labor intensive and time consuming process cannot be completed within the current budget and timetable. We are currently budgeting approximately \$30,000/month to contact subjects without a sufficient number of interviews being conducted. A summary of our progress to date is in Exhibit 1 (below).

We have confirmed with Battelle's Survey Operations group that this study is unique among CATI (Computer Aided Telephone Interview) studies of this size in requiring written consent forms. All their CATI studies rely on verbal consent.

We are requesting that Verbal Consent be allowed for the CATI portion of this study. The proposed verbal consent script is in Exhibit 2 (below). A copy of this form will be mailed to each subject who gives verbal consent so that they may keep it in their records.

B) Appreciation Gift

It seems clear to us that it is necessary to distinguish our request from the many requests received by people every day. We believe that inclusion of a \$5 appreciation gift will accomplish this goal.

We are requesting that a \$5 appreciation gift be sent to all subjects giving verbal consent for the CATI interview. This gift would be included in the "informed consent information packet" to be mailed to each participant once verbal consent is given.

C) Written Consent for Medical Records

Problems encountered with our first mailing will be largely resolved if we have already contacted, obtained verbal consent and interviewed participants prior to requesting written consent for medical records.

However, to expedite and speed up the process of collecting these consent forms, we propose to get these forms to subjects by one of three means. They are listed in the order of preference:

- 1st - The consent form will be faxed to the subject – the subject will sign the form and fax it back. This provides for the quickest turn around time and the lowest probability that the response will get lost among the many other obligations of the subject.
- 2nd - The consent form will be e-mailed to the subject – the subject will then print it out, sign it, and mail it back. These extra steps will reduce the return rate.
- 3rd - The consent form, along with a postage paid return envelope and an appreciation gift, will be included in the "informed consent" information package being sent to the subject (as described above).

In any case, a signed hard copy of the consent form will be obtained prior to any review of medical materials.

Modification #2: CATI Questions

Add 22 new questions to the CATI.

We have determined that Social-Economic Status may be an important confounder in our study, and that the interpretability of the results will be significantly improved with the addition of these questions. The questions are interspersed throughout the CATI and are summarized in Exhibit 3 (below). These questions do not represent any significant increase in the sensitivity of the data being collected, and would only add a few minutes to the duration of the interview.

Modification #3: Follow-Up Contacts

We believe it may be necessary to re-contact some subjects to update or confirm information.

We believe that when we review the CATI questionnaires, and when we try to obtain medical histories, we will run into situations where additional information, clarification and/or confirmation of information may be required. We are requesting permission to re-contact subjects to obtain this information. These contacts will be minimal in demand, and WILL NOT be used to obtain new areas of information not previously approved by the review board.

Exhibit 1
Background Data on Study Outreach

All Sources (NOTE – will not include all data from last 2.5 weeks)

Total Mailing	~7,000	
Total Contacted	434	(434/7000 = 6% contacted)
Total Contacted & Agreed	357	(357/7000 = 5% agreed)
Total Set Up for CATI interview:	301	(remaining 56 to be set up)
Already interviewed	257	(remaining 44 to be interviewed)

Phone Calls:

Total Calls	~3,300	
Unique ID's called	2,084	
Last 2.5 weeks	~1,400	
Unique ID's called	800	

Breakdown of Calls for last 2.5 weeks

Total Calls	1,400	
Total contacts	130	
Had received packet	35	(Packet sent to remaining 95)
Verbally Agreed	40	(Remaining 90 are considering)

Note:

1. Virtually NO outright refusals, most simply requested packet be sent.
2. 130 contacts/1400 calls (10.8 calls per contact)
3. Only 35/130 (27%) remembered seeing the packet

Exhibit 2 Verbal Consent Script

Introduction:

It is important that you listen to and understand the following general principles that apply to all who take part in Air Force sponsored research studies.

- 1st - taking part in this study is entirely voluntary;
- 2nd - you may have no personal benefit from your participation in this study, but knowledge may be gained that will benefit others;
- 3rd - you may withdraw from the study at any time without penalty or loss of any benefits to which you are otherwise entitled.

Purpose:

You are being asked to participate in a study of pregnancy, miscarriage, and births among both former and current active duty Air Force women. The Air Force has an excellent record of supporting active duty women who become pregnant, and has allowed women who become pregnant to remain on active duty since 1975. Earlier studies have shown that birth rates among active duty Air Force women generally exceed those of the US working population. Air Force women also have better pregnancy outcomes, reflecting their good health, excellent health benefits, and the safety of Air Force workplaces. Nevertheless, it is possible that some of the many varied Air Force work environments may have less than satisfactory pregnancy outcomes. This study intends to investigate these connections with the hope of preventing unsatisfactory pregnancy outcomes among active duty Air Force women in the future.

In particular, this study will evaluate three pregnancy outcomes; high blood pressure during pregnancy, miscarriage, and early or pre-term delivery. Associations between these outcomes and a broad range of personal and work-related factors, previously suspected as possible risk factors, will be evaluated. You have been randomly selected for this study from pregnancy records for the years 1990 through 1998, which were provided to us by the Air Force. You may have experienced one of these outcomes, or may have had a completely normal delivery.

Specific Procedures:

The study will be conducted over a two-year period and will include approximately 1,900 pregnancies with one of the three outcomes being studied, and an additional 1,900 pregnancies without any complication. If you decide to participate, the following is required:

- 1) verbal permission to schedule me for a telephone interview to be conducted at my convenience, and
- 2) written permission to use my pregnancy-related Air Force inpatient and outpatient medical records.

The telephone interview, which will take an hour or less, will collect information on:

- your work history over a period starting three months prior to conception and continuing until the end of that pregnancy
- a review of chemicals (including solvents, metals, pesticides, etc.) and other factors (including level of physical activity, stress, noise, vibration, etc.) you may have encountered in your workplace during your pregnancy
- a brief medical history with associated medications
- a reproductive history including voluntary abortions
- your personal habits, including smoking and alcohol consumption, during each pregnancy

Benefits:

You should understand that no benefit can be guaranteed. You may not directly benefit from the findings of this study. However, it is hoped that this study will establish a better understanding of the relationships between personal characteristics, Air Force workplaces, and pregnancy outcome among active duty Air Force women. You will receive a \$5 appreciation gift for your participation.

Alternatives:

You have the alternative of not participating in this study.

Risks and Inconveniences:

Your only risk from participation in this study is the possible loss of privacy and confidentiality. While it is possible that your personal and medical information could be unintentionally released, the investigators for this study will be taking stringent precautions to avoid this. First, the investigators will remove your identifiers, including your name and Social Security Number, from all data files and store them separately. Codes, known only to the research team, will be used to identify your records. Second, all the data will be stored in a secured area with access limited to the investigators. Your name will never appear on any reports and only summary information will be published. The information collected for this study will be kept secure and maintained for five years from the completion of the study. At that time, it will be destroyed.

Decision to Participate:

You should understand that this study is in compliance with standards for treatment of human subjects by our various research institutions and the US Air Force.

This investigation is a Defense Advisory Committee on Women in the Services (DACOWITS) study. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research.

I understand copies of an Executive Summary of this study can be obtained by requesting a copy from the following address:

Air Force Women's Health Study
Battelle CPHRE, 100 Capitola Drive, Suite 301
Durham, NC 27713-4411

or by calling (919) 544-3717 and asking for the Air Force Women's Health Study representative.

Before you agree to participate in this study, do you have any questions or concerns?

Respond to any questions

Your decision to participate in this study must be completely voluntary, without any coercion or intimidation. Are you participating because you want to?

If NO, record information on concerns

Investigators will be available to answer any questions concerning procedures throughout this study. Their names and contact numbers will be mailed to you along with a written version of this informed consent procedure. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed. You may withdraw this consent at any time and discontinue further participation in this study without prejudice to any entitlement.

You should understand that you may refuse to participate in all or any part of this study, or refuse to answer any specific question without penalty. All personal information obtained will be considered

privileged and held in strict confidence. Your identity will remain private. You will not be identified in any presentation of the results. No individual data about you will be released; only summary data will be published.

Consent:

1. Have you heard and understand the purpose and benefits, procedures, and risks associated with your participation in the study.
If Yes, continue. If NO, respond to questions.
2. Do you agree to participate in the study.
If Yes, continue. If NO, thank them for their time.
3. Do you wish to participate in the one-hour interview right now?
If Yes, continue. If NO:
4. Would you like to schedule the interview now?
If Yes, schedule. If NO:
4. Do you give permission for the study researchers to schedule a one-hour interview at my convenience.

Exhibit 3
20 Additional CATI Questions

I) *Demographic section*

A) Questions about Your Parent's or Legal Guardian's Job & Education.

1. What was your mother's (or legal guardian's) occupation or longest held job? (probe for the major job)

String

2. What type of place or in what type of industry did she work? (distinguish large from small companies)

String

3. What was your mother's (or legal guardian's) highest level of education?

1=HS/GED 2=2 years college 3=BA/BS 4=Higher ED -1=DK

4. What was your father's (or legal guardian's) occupation or job ? (probe for the longest held job)

String

5. What type of place or in what type of industry did he work? (distinguish large from small companies)

String

6. What was you father's (or legal guardian's) highest level of education?

1=HS/GED 2=2 years college 3=BA/BS 4=Higher ED -1=DK

7. Between the ages of 5 to 15 did you live with both your parents or with a single parent or legal guardian?

1=Both 2= Single -1=DK

8. Why did you enter the AF?

String

B) Questions about Your Social Life

9. List how many different organizations (any routine groupactivity) you were a member of in 2 year period before you entered the AF.

e.g. church, school, sports team, club, bridge game, outing, gym, volunteer org, museum, music, choir....(*String*)

10. List how many different organizations (or any routine groupactivity) you were a member of in the year of this index pregnancy.

e.g. church, school, sports team, club, bridge game, outing, gym, volunteer org, museum, music, choir....(*String*)

11. Did you experience any form of discrimination prior to entry into the AF?

1=Yes 2= No -1=DK

12. Did you experience any form of discrimination during the year of the index pregnancy?

1=Yes 2= No -1=DK

C) Questions about Material and Emotional Support from Parents

13. Did you receive material support from your parents?

- In the 2 year period before entering the AF?

1=Yes 2= No -1=DK

- In the year of this index pregnancy?

1=Yes 2= No -1=DK

14. How many times (wk/month/yr) did you communicate with members of your family?

- In the 2 year period before entering the AF?

___/wk ___/mo ___/yr

- In the year of this index pregnancy?

___/wk ___/mo ___/yr

15. Were you taught to cook by your family?

1=Yes 2= No -1=DK

16. How frequently did you cook with the family?

___/wk ___/mo ___/yr

17. Did your family separate the laundry so dirty work clothes were washed separately from other clothes?

1=Yes 2= No -1=DK

II) *Medical Section*

18. During this pregnancy were you informed that you had...

Diabetes 1=Yes 2= No -1=DK

Anemia 1=Yes 2= No -1=DK

Asthma 1=Yes 2= No -1=DK

Weight under 70 K 1=Yes 2= No -1=DK

19. After this (normal birth/PIHT/PT/SA), did you have trouble returning to your former weight?

1=Yes 2= No -1=DK

20. Did you have trouble complying with AF weight regulations?

1=Yes 2= No -1=DK"

IRB Response from Travis AF Base

Our request was submitted in May 2000 but was not reviewed until July 2000. During this time we only worked on data analyses of Phase I data. We did not receive a written response from Travis IRB but did get an email and telephone call from our IRB contact Monica Easley. In summary, the board rejected our request to eliminate the consent form, but did approve the new questions, the gift, and multiple procedures for contacting women. We started to resume data collection in August 2000.

Obtaining a consent form introduced a massive change in scope from what was originally approved in the original proposal. We had originally proposed to call each woman to schedule a CATI. Now we have to mail, phone, and track two consent forms in triplicate from all women. The process resulted in adding 34 new part-time research assistants (~10 FTE) to complete the work at considerable expense. It also introduced a one year delay in data collection.

2. Revise the CATI

Based on the new information obtained from the IRB in August, we revised CATI V10 to include new questions. The programming took 1 week and call backs to the first 264 women who had already completed the first CATI without the new questions was completed during the months of August-December. In addition, we revised our large training manual, QxQs for interviewers, the supervisor's manual, telephone scripts, and code book.

3. Ascertain Permission from 82 Air Force Bases and Minor Installations

Concurrent with the human subject activity, the research team initiated in February 2000 the significant preparatory steps to obtain access to relevant confirmatory data from CONUS AF Bases (major and minor installations). The first step was to obtain a letter from the AF Surgeon General. A packet was assembled containing 9 documents listed below and was sent to 8 major commands.

1. AFMOA/CC letter dated, 29 Jan 1999
2. Study Talking Paper
3. Briefing Slides
4. Battelle IRB Approval Letter
5. University of Texas Health Science Center IRB Approval Letter
6. Army and Air Force IRB Letters (will be forwarded upon receipt)
7. Study Pamphlet
8. Informed Consent Document
9. Medical Records Release Form

Contacts at each of the eight major commands provided the research team with a point of contact for each AF Base. These individuals will change over time but all will have the advantage of being located at each AF Base of research interest. They, in turn will inform the Base Commander of all study activity. From our perspective, the Base Commanders within most of the commands are now aware of

the scope and the extent of their involvement in the research project. Our list of contacts includes POCs from each of the CONUS AF Bases.

U.S. BASES	State	Command
Altus AFB	OK	AETC
Andrews AFB	MD	AMC
Arnold AFB	TN	AFMC
Barksdale AFB	LA	ACC
Beale AFB	CA	ACC
Bolling AFB	DC	DRU
Brooks AFB	TX	AFMC
Cannon AFB	NM	ACC
Charleston AFB	SC	AMC
Columbus AFB	MS	AETC
Davis-Monthan AFB	AR	ACC
Dover AFB	DL	AMC
Dyess AFB	TX	ACC
Edwards AFB	CA	AFMC
Eglin AFB	FL	ACC
Eielson AFB	AK	PACAF
Ellsworth AFB	SD	ACC
Elmendorf AFB	AK	PACAF
Fairchild AFB	WA	AMC
F.E. Warren AFB	WY	AFSPC
Goodfellow AFB	TX	AETC
Grand Forks AFB	ND	AMC
Hanscom AFB	MA	AFMC
Hickam AFB	HA	PACAF
Hill AFB	UT	AFMC
Holloman AFB	NM	ACC
Hurlburt Field	FL	AFSOC
Keesler AFB	MS	AETC
Kelly AFB	TX	AETC
Kirtland AFB	NM	AFMC
Lackland AFB	TX	AETC
Langley AFB	VA	ACC
Laughlin AFB	TX	AETC
Little Rock AFB	AR	ACC
Los Angeles AFB	CA	AFMC
Luke AFB	AZ	AETC
MacDill AFB	FL	AMC
Malmstrom AFB	MT	AFSPC
Maxwell AFB	AL	AETC
Maxwell AFB Gunter Annex	AL	AETC
McChord AFB	WA	AMC
McClellan AFB	CA	AFMC
McConnell AFB	KA	AMC
McGuire AFB	NJ	AMC
Minot AFB	ND	ACC
Moody AFB	GA	ACC
Mountain Home AFB	ID	ACC

Nellis AFB	NV	ACC
Offutt AFB	NE	ACC
Onizuka AS	CA	AFSPC
Patrick AFB	FL	AFSPC
Peterson AFB	CO	AFSPC
Pope AFB	NC	AMC
Randolph AFB	TX	AETC
Robins AFB	GA	AFMC
Schriever AFB	CO	AFSPC
Scott AFB	IL	AMC
Seymour Johnson AFB	NC	ACC
Shaw AFB	SC	ACC
Sheppard AFB	TX	AETC
Tinker AFB	OK	AFMC
Travis AFB	CA	AMC
Tyndall AFB	FL	AETC
USAF Academy	CO	DRU
Vance AFB	OK	AETC
Vandenberg AFB	CA	AFSPC
Whiteman AFB	MO	ACC
Wright-Patterson AFB	OH	AFMC

MINOR CONUS INSTALLATIONS/SITES

Avon Park AS	FL	ACC
Cape Canaveral AS	FL	AFSPC
Cape Cod AS	MA	AFSPC
Cavalier AS	ND	AFSPC
Cheyenne Mountain AS	CO	AFSPC
Clear AS	AK	AFSPC
Dobbins ARB	GA	AFRC
Duke Field AS	FL	AFSOC
Earekson AS	AK	AFSPC
El Dorado AS	TX	AFSPC
Fort Eustis	VA	ACC
Fort Hood	TX	ACC
Fort Gordon	GA	AETC
Galena Airport	AK	PACAF
Gila Bend AF Auxiliary Fld	AZ	AETC
Indian Spring AF Aux Fld	NV	AFSPC
King Salmon Airport	AK	PACAF
Maui AS	HA	AFMC
New Boston AS	NH	AFSPC
Onizuka AS	CA	AFSPC
Rome AF Research Laboratory	NY	AFMC

4. Ascertain the Final Cohort

Seven sources of data were used to obtain access to the cohort. They include five military data sources: Standard Inpatient Data Record (SIDR), Central Researcher's Database (CRDB), Air Force

Inpatient Data System (also known as Pentagon), Defense Manpower Data Center (DMDC), and the Air Force Personnel Center's Worldwide Locator (WWL). In addition, two civilian data sources have been used: Transunion LLC (TU) and the National Change of Address (NCOA).

Battelle placed the request to Brook AF personnel on October 5th 1998 and received the Standard Inpatient Data Record (SIDR), the Central Researcher's Database (CRDB), and the Air Force Inpatient Data System (also known as Pentagon Data) on August 18 1999. A request for updated addresses from the Air Force Personnel Center's Worldwide Locator (WWL) data set was requested and received over the period of September to November 2000.

History of Subject Ascertainment

On October 5, 1998, we sent the AF a final request to ascertain all eligible cases and controls from January 1, 1990 to December 31, 1998. Briefly, the request was made to the Population Health Support Office (PHSO) at Brooks Air Force Base, Texas. The criteria consisted of the following:

- all events with a ICD-CM9 code of 634, 642, 644, or 650,
- the women must have been on Active Duty status at the time of the event, and
- the event must have occurred between January 1, 1990 and December 31, 1998.

PHSO fulfilled that request by providing three electronic datasets to the research team; one file each from the SIDR, Pentagon, and the CRDB. A distribution of those data is contained in the table below. The original CRDB file contained 7,541 events. However, 795 of those events occurred in 1989 and were withdrawn from the sample. Also, the original Pentagon file contained 7,899 events and 1,435 of those events did not have an admission date and were withdrawn from the sample.

Subject and Event File Distribution

Source	Available Events	Non-duplicate Events	Selected Events (1 st /subject)	Selected PIH Events	Selected PT Events	Selected SA Events	Selected Normal Events
SIDR	8507	8507	7850	1160	1364	1566	3760
CRDB ₁	6746	1213	1077	80	142	49	806
Pentagon ₂	6464	6	5	2	2	0	1
Totals		9726	8932				

¹ The original CRDB file contained 7541 Events. However, 795 of those events occurred in 1989 and were withdrawn from the sample. ² The original Pentagon file contained 7899 Events. However, 1435 of those events did not have an admission date and were withdrawn from the sample.

Battelle received a valid sample in August 1999. The 9 month effort involved tremendous dedication and level of effort on the part of AF personnel who sliced together data tapes. It took from October to June to gain access to the data and from June to August to actually receive the data. A duplicate run yielded the same values so the entire research team is confident that we have obtained a valid set of subjects.

Note that the SIDR data is the primary source of the events. However, the SIDR only contains admissions that occurred at military treatment facilities. Additional cases and controls were also selected from the CRDB and Pentagon datasets since they contained events that occurred at both

military and civilian medical treatment facilities. Once all non-duplicate events were identified and the first occurrence for each woman was selected as the study event.

Further, due to occupational omissions in the SIDR, The CRDB and Pentagon datasets served as the primary sources for job and duty location information where second and third jobs and some missing duty information was only available through the DMDC dataset.

Described below is a history of our SIDR activity over the entire project including this year.

History of Battelle's Requests for the SIDR Air Force Dataset

Date	Event
10/14/98:	First letter sent by Diana Echeverria (PI) to Brooks AF Base (John Mellman) requesting the cases and control be pulled. This letter included the criteria and definition of events as well as the demonstrated subset from 1990-1994.
11/17/98:	All research staff was present at a conference call including John Mellman where we discussed the data pull.
11/23/98:	Kevin Grayson, Nick Heyer, and Steve Wilkins resubmitted a more refined set of definitions to John Mellman. This included SIRD and CRDB variable listings.
12/18/98:	John Mellman said he needed AF IRB approval but he would pull the data now and have it ready in December (not done).
01/12/99:	Diana Echeverria (PI) and Kevin Grayson (AF) met with John Mellman and Mike Snedecor in San Antonio. We reiterated our request that he prepare data file to be ready once Air Force IRB approval is received.
02/10/99:	Steve Wilkins met with John Mellman in San Antonio. John Mellman gave us a preliminary event count at that meeting and we asked that he prepare the data file to be ready once Air Force IRB approval received.
04/12/99:	PI resent SIRD and CRDB variable listings to John Mellman.
04/22/99:	Requested progress on the dataset from John Mellman and sent a second more formal request letter to Major Snedecor.
05/04/99:	Major Snedecor gave John Mellman his approval to release data.
06/18/99:	Battelle received the initial SIDR & CRDB datasets from John Mellman.
06/21/99:	Battelle converted the SAS data format to dbf format - partially worked.
06/22/99:	Battelle notified John Mellman that date fields were formatted as SAS text strings not SAS date fields. John Mellman was asked if he would resubmit files in proper format.
06/28/99:	Battelle requested contact information (phone and address) from DMDC. We received a date corrected(?) dataset from John Mellman but no duty zip on 1996-1998 data. We requested that Roger Gibson access the data from California Manpower. Roger Gibson agreed to assist the team and felt it should be no problem - at most 1 week.

07/26/99: Battelle received a new CRDB dataset from John Mellman which contained some births not in the SIDR among women who delivered in non military hospitals but no cases beyond 1996. Further 1,800 subset of the SIDR dataset was also resent to Roger 07/27/99: with a second request to provide duty zips and UIC fields. After reviewing the received dataset Battelle found it was a recreation of the first dataset and did not contain more info for events between 6/96 and 12/98. John Mellman concluded that he could not provide us with the missing data.

Summary

Entire SIDR -1990-1998 missing zero duty on all subjects

CRDB 1990-1996 has duty zip on a subset but also is missing 1996-1998 data

DMDC 1996-1998

08/23/99: Battelle finally received a duty zip and uic dataset from DMDC but it only contained 106 subjects (we needed 1,800).

08/25/99: Battelle notified Shari Shanklin (Roger Gibson's DMDC contractor) that dataset only contained 106 records. Format was discussed. Support staff went on vacation for three weeks. Was notified by Shari that no work could be done until September.

09/15/99: Battelle was notified we should receive 1,800 subjects' dutyzip data sometime this month.

11/29/99 Battelle received the complete Manpower dataset.

12/31/99 Battelle formatted the Manpower data set

01/01/00 Missing demographic data normally found in the CRDB has been requested for ~1,200 subjects from the period between June 1996 to Dec 1998. We have not received this information to date.

Distribution of ICD 650 – a research concern

We reexamined the distribution of subjects by base and found that the number of normal events was dramatically lower than expected. As seen below, the ICD Code "650" is for a normal birth and the prevalence of events decreased over time. We examined the number of events and their percentage over all events from 1990 to 1998. The percentage dropped from 11% to ~2%. We believe that trends in coding are affected by insurance forms and other AF medical care factors. However, we also believe this code is the most valid code for a normal birth. Therefore, we decided to alter our study to include all CONUS AF Bases in order to obtain our target of 650 subjects for each type of case and control.

	1990			1995	
	ICD9CM	Events	%	Events	%
SA	634	352	3.972	147	1.659
PIH	642	180	2.031	121	1.365
PT	644	212	2.392	153	1.726
Normal	650	1001	11.294	388	4.378
	Totals:	1745	19.689	809	9.128
	1991			1996	
	ICD9CM	Events	%	Events	%
SA	634	285	3.216	106	1.196
PIH	642	150	1.692	133	1.501
PT	644	205	2.313	123	1.388
Normal	650	853	9.624	279	3.148
	Totals:	1493	16.845	641	7.232
	1992			1997	
	ICD9CM	Events	%	Events	%
SA	634	236	2.663	52	0.587
PIH	642	158	1.783	128	1.444
PT	644	207	2.336	115	1.298
Normal	650	694	7.830	189	2.132
	Totals:	1295	14.611	484	5.461
	1993			1998	
	ICD9CM	Events	%	Events	%
SA	634	191	2.155	27	0.305
PIH	642	122	1.377	122	1.377
PT	644	208	2.347	120	1.354
Normal	650	515	5.811	181	2.042
	Totals:	1036	11.689	450	5.077
	1994			Totals	
	ICD9CM	Events	%	Events	%
SA	634	185	2.087	1581.00	17.84
PIH	642	126	1.422	1240.00	13.99
PT	644	154	1.738	1497.00	16.89
Normal	650	445	5.021	4545.00	51.28
	Totals:	910	10.267	8863.00	100.00

5. Ascertain Contact Information (names, addresses, and phone numbers)

The task of ascertaining contact information is central to the success of the project. The list of 8,932 subjects was submitted to (a) DMDC and (b) Transunion with a social security number and date of birth. The combined file was then updated using the World Wide Locator. These steps are repeated once during November 1999, again during February 2000 and again during November 2000.

(a) DMDC

Within two months of time from the initial request, the DMDC provided address information on 5,045 of those subjects. The DMDC had no data for the remaining 3,883 subjects. Further, the DMDC dataset did not contain a zip code field and was returned to DMDC in order to obtain complete names and

addresses for all 5045 subjects that the DMDC had on the file (5 had insufficient data). We received the updated dataset on November 26, 1999.

(b) Transunion

With respect to the initial file of 8,932 subjects sent to Transunion LLC, we received over 104,904 addresses and names for 7,850 women. A second request was made to Transunion for the remaining 1,082 not previously obtained. Addresses and names were provided for 1,076 women. There was no information available for the remaining 6 subjects where it was assumed that the social security number was incorrect (this was verified using DMDC data). The two Transunion datasets were combined and multiple occurrences of the same address were deleted leaving 30,480 possible addresses with recent dates from Transunion LLC.

(c) World Wide Locator

The same list of 8,932 subjects was then submitted to the Air Force Worldwide Locator office at Randolph Air Force Base, Texas. The goal was to determine active duty status and current address. The first file provided by the WWL failed to contain a link between the social security numbers provided by the research team and the contact information supplied by the WWL office. A second file was generated to link social security numbers with the names and addresses provided by the WWL. The WWL was then able to successfully match and provide us with 5,410 addresses; the work address for all active service subjects and the home address for all retired subjects. Further, we were also able to obtain current duty information as part of the WWL dataset. The final distribution of the subject duty status is described in the table below.

Duty Status	Count
Active Service - Stateside	4323
Active Service - Overseas	771
Separated	3295
Retired	423
Deceased	4
Protected Airmen	4
Serving in Other Branch of Service	63
Deserted	1
Unknown/No Record	48

As described above, the process of selecting a working address is very complex. First, all addresses from the DMDC dataset (N = 5,050) and the address with most current source date from the Transunion datasets (N = 8,932), were resubmitted to the NCOA. We deleted from both these datasets, subjects who were located overseas, subjects who were deceased or deserted, subjects who were protected, and subjects employed in other military branches of service. This left us with 8,041 eligible subjects.

NCOA received the data set containing 8,041 subjects and updated 832 addresses from the DMDC source and 1,117 addresses from the Transunion source. The changes from both sources were combined and duplicates removed leaving 1,571 unique addresses from NCOA.

We then combined the different address sets into a single dataset of 42,506 potential final addresses. The distribution of cross-referenced address from the different datasets is provided in the next table. Through this process, we can now define the study population as n=8,036.

Source	Received	Updated DMDC	Updated TransUnion	Matched NCOA
NCOA	8,041	832	1,117	1571

Source	Available Addresses	Matched DMDC	Matched TransUnion	Matched NCOA	Matched WWL	Used Initial Mailing
DMDC	5045	5045	248	180	467	4
TransUnion	30480	248	30480	46	53	2827
NCOA	1571	180	46	1571	40	456
WWL	5410	467	53	40	5410	4749
						8,036

Contact Data Correlation

6. Ascertain Phone Numbers

Obtaining telephone numbers is considerably simpler. The list of 8,036 women's names and addresses was sent to the National Telematch Telephone Directory, a service that matches names and addresses with telephone numbers.

TeleMatch found phone numbers for 3,549 of the civilian records of which 906 are duplicates. Given, 4,323 are still on active duty, it will be easy to contact these women directly on the AF Base. However follow-up efforts to track these women has proven to be very difficult.

7. Design a Tracking Database

In December 2000 the 8,036 cases and controls were entered into a tracking database that contains seven screens. This tracking database is our primary management tool that is used to run the study. It maintains addresses, phone calls, follow-up interactions, CATI dates, reports, mailing dates, and file transfers. The goal is to have study assistants track the status of subjects with respect to ascertaining consent and medical release forms, number of attempts and contacts by phone, and scheduling. A report generator tracks our progress. Initially, the information already collected on duty location and assignment at time of hospitalization for pregnancy, event dates and outcomes, current addresses and phone numbers are loaded into the program. These are updated as the study progresses. The screens are described below.

The first screen summarizes information on the subject, and, using a set of tracking variables, identifies the subject's progress through the study (see the Data Dictionary in Appendix B, 1999).

Air Force Women Reproductive Outcomes & Risk Factors Study - Mail Mode

Subject Info | **Address** | Phone | Follow-Up | History | Tracing | Messages | Reports

SubjectID Rank First Name Middle Name Last Name Alias

Active Address

Other Addresses

DATE	CODE	PRIORITY	ADDRESS
200012	2	1	
199912	0	3	
199908	0	4	
199904	0	4	
199903	0	4	
199902	0	4	

Address Code

- No Action Taken
- Valid Work
- Valid Home
- Valid Other
- Incomplete
- Invalid
- Forwarded Address

Address Priority

- No Action Taken
- Valid Primary
- Valid Secondary
- Active
- Rejected

Address Source Date

YYYYMM | 200012

Comments

VALID ADD SUBJ CONFIRMED. 12/20/2000 - MT

Add Edit Save Undo

Edit Save << >> Find By SubjectID Find By Name >> >>| Undo Main Menu

Dates of completion for subjects to complete each phase of the study are recorded in the lower left of this screen. Check boxes keep track of whether or not we have received informed consent, medical release and medical record documents.

The second and third forms are used for tracing subjects. We have multiple addresses and phone numbers on many of the subjects, and many may have moved or changed phone numbers since these data were obtained. These forms are used to track which phone numbers are or are not valid. Addresses or phone numbers from the grids on these screens may be made active by clicking on them. This brings the information into the editing fields, where the information may be corrected and assigned a status of valid or invalid (for various reasons). A new record of information may be added for any subject (see below).

Air Force Women Reproductive Outcomes & Risk Factors Study

Subject Info | **Address** | Phone | Follow-Up | Reports | Mailing | File Transfer

SubjectID Rank First Name Middle Name Last Name Alias

Active Address

Other Addresses

SubjectID	Source	Address
9912	1	43 MISSION SUPPORT SQ/DFMAR
9908	2	
9907	3	
9805	4	
9805	5	

Address Code

- Valid Primary
- Valid Work
- Valid Secondary
- Valid Home
- Incomplete
- No Action Taken
- Rejected
- Invalid

Comments

CLICK AN ADDRESS TO MAKE IT ACTIVE

Add Edit Save Undo

Edit Save End >> >>| Quit

Air Force Women Reproductive Outcomes & Risk Factors Study

Subject Info | **Phone** | Follow-Up | Reports | Mailing | File Transfer

SubjectID Rank First Name Middle Name Last Name Alias

Active Phone Numbers

Valid Phone Numbers

Other Phone Numbers

SubjectID	CITY	STATE	AreaCode	LocalPhone	Pho
		NC			
		NC			
		NC			

Phone Code

- No Action Taken
- Valid Home
- Valid Work
- Valid FAX
- Valid Other
- Active - No Answer
- Active - Machine Message
- Active - Person Message
- Disa Line
- Timed Out
- Not in Service
- Wrong Number
- Invalid - Other

Phone Status

- No Action Taken
- Contacted
- Active

Comments

CLICK A PHONE NUMBER TO MAKE IT ACTIVE

Add Edit Save Undo

Edit Save End >> >>| Quit

As there are over 8,000 women who may be called during this study, keeping a clear record of tracking procedures is essential. The next screen will be used by study assistants to keep track of who they have called, and the outcomes of these calls (see below). It is also during these calls that

the majority of the updating of the above screens will be done. Moving from one screen to another is as simple as clicking on a tab.

Additional screens track our mailings and their returns, file transfers (medical records and consent forms) between research teams and reports.

For example, the series of tables below were generated by our weekly reports summarizing project activity. Tallies for active duty and inactive women are summarized separately and together for mailing, tracing, follow-up, interviewing, and completion of the CATI.

Study Summary as of 1/11/2001	Active Duty		Non-ActiveDuty		Total
	N	%	N	%	N
Inactive					
Not Eligible	929	85.94%	152	14.06%	1081
Soft Refusals	89	70.08%	38	29.92%	127
Hard Refusals	198	66.89%	98	33.11%	296
Inactive SubTotal	1216	80.85%	288	19.15%	1504
Active					
Mailing	72	55.81%	57	44.19%	129
Tracing	170	29.31%	410	70.69%	580
Followup	2969	52.48%	2688	47.52%	5657
Interviewing	147	66.22%	75	33.78%	222
Completed	520	61.90%	320	38.10%	840
Active SubTotal	3878	52.21%	3550	47.79%	7428
Study Total	5094	57.03%	3838	42.97%	8932

The high proportion of active to non-active duty status women reflects our decision to use a ratio of 2:1 to maximize returns on women with better known addresses. This sampling frame will change as more women leave the Air Force. In January 2000, roughly one half of the potential subjects were still employed in the Air Force. One year later, a quarter of the subjects are still in the Air Force.

Outcome Distribution	Eligible		Accepted		Consents		Interviewed	
	N	%	N	%	N	%	N	%
Active Duty								
Normal Delivery	1958	26.36%	422	34.82%	324	30.42%	256	30.48%
PreTerm Delivery	689	9.28%	150	12.38%	128	12.02%	107	12.74%
Pregnancy IHT	569	7.66%	135	11.14%	96	9.01%	74	8.81%
Spontaneous Abortion	662	8.91%	142	11.72%	121	11.36%	83	9.88%
Active Duty SubTotal	3878	52.21%	849	70.05%	669	62.82%	520	61.90%
NonActive Duty								
Normal Delivery	1864	25.09%	166	13.70%	167	15.68%	137	16.31%
PreTerm Delivery	558	7.51%	68	5.61%	83	7.79%	70	8.33%
Pregnancy IHT	461	6.21%	48	3.96%	55	5.16%	41	4.88%
Spontaneous Abortion	667	8.98%	81	6.68%	91	8.54%	72	8.57%
NonActive Duty SubTotal	3550	47.79%	363	29.95%	396	37.18%	320	38.10%
Study Totals								
Normal Delivery	3822	51.45%	588	48.51%	491	46.10%	393	46.79%
PreTerm Delivery	1247	16.79%	218	17.99%	211	19.81%	177	21.07%
Pregnancy IHT	1030	13.87%	183	15.10%	151	14.18%	115	13.69%
Spontaneous Abortion	1329	17.89%	223	18.40%	212	19.91%	155	18.45%
	7428	100.00%	1212	00.00%	1065	100.00%	840	100.00%

Recruitment Effort		Active Duty		Non-Active Duty		Total
		N	%	N	%	N
Follow-up Status						
	No Action Taken	91	53.22%	80	46.78%	171
	Actively Calling	1184	66.07%	608	33.93%	1792
	Contacted - Accepted	742	74.57%	253	25.43%	995
	Contacted - Maybe	137	76.97%	41	23.03%	178
	Subject Contact Research Team	25	67.57%	12	32.43%	37
	Soft Refusals	85	70.83%	35	29.17%	120
	Hard Refusals	194	67.83%	92	32.17%	286
	Timed Out	81	68.07%	38	31.93%	119
Total Recruitment Contacts		2367	69.45%	1041	30.55%	3408

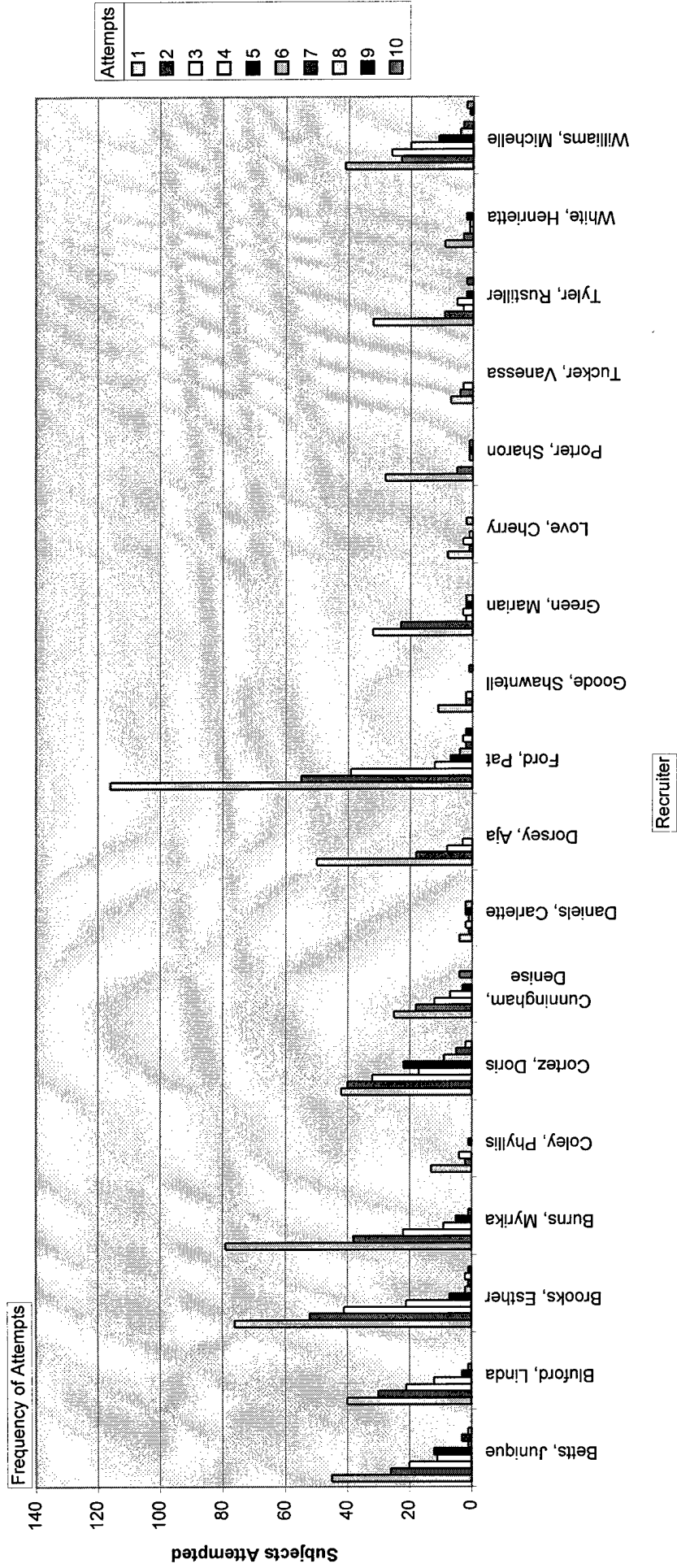
Tracing Status Report	Active Duty		Non-Active Duty		Total
	N	%	N	%	N
Actively Tracing	173	35.67%	312	64.33%	485
Tracing Completed	658	49.36%	675	50.64%	1333
Tracing Required	219	74.24%	76	25.76%	295

The outcome distribution is dependent on the recruitment and tracing efforts. To date, all women have been mailed a packet and 3,408 women have been contacted by phone at least once. Among these, at least one half have had some degree of difficulty either in obtaining a correct phone number or address. These women have been sent to a tracing team of four research assistants. Once they have been successfully traced their IDs are placed back into the recruitment pool where a separate team of recruiters pick them up in order to obtain their consent form.

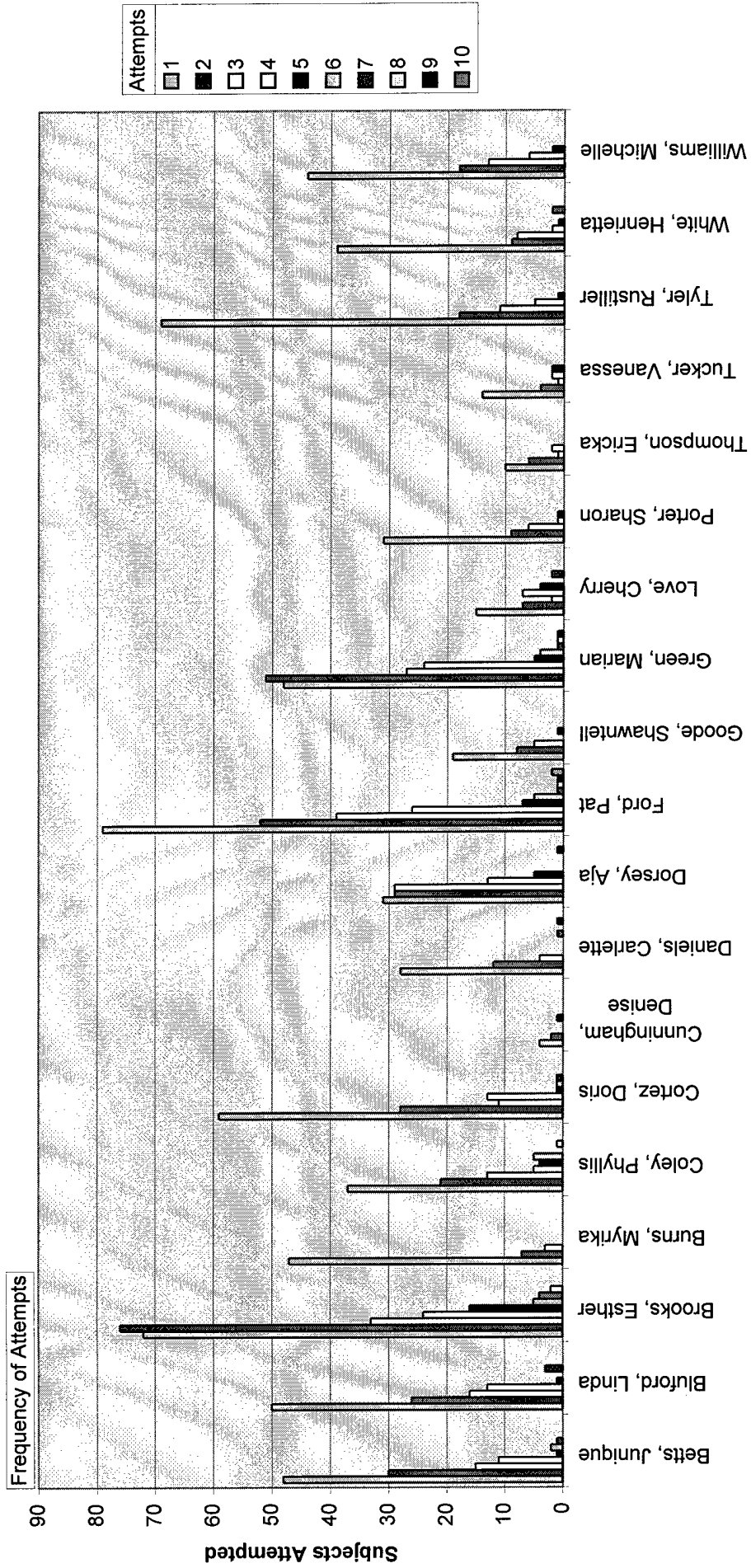
The number of phone calls per subject to ascertain a consent form is presented in the next series of graphs. We print these tables to track individual's productivity and to make sure we avoid entrapment

within a sub sample of subjects. Note that we do not permit more than 10 calls per subject. In addition, tracking the time of day permits us to see when we are more successful at finding women. The results indicated that we are only slightly more successfully at finding women in the mornings than in the afternoons and evenings, but the difference is not very great.

Weekday Morning Histogram

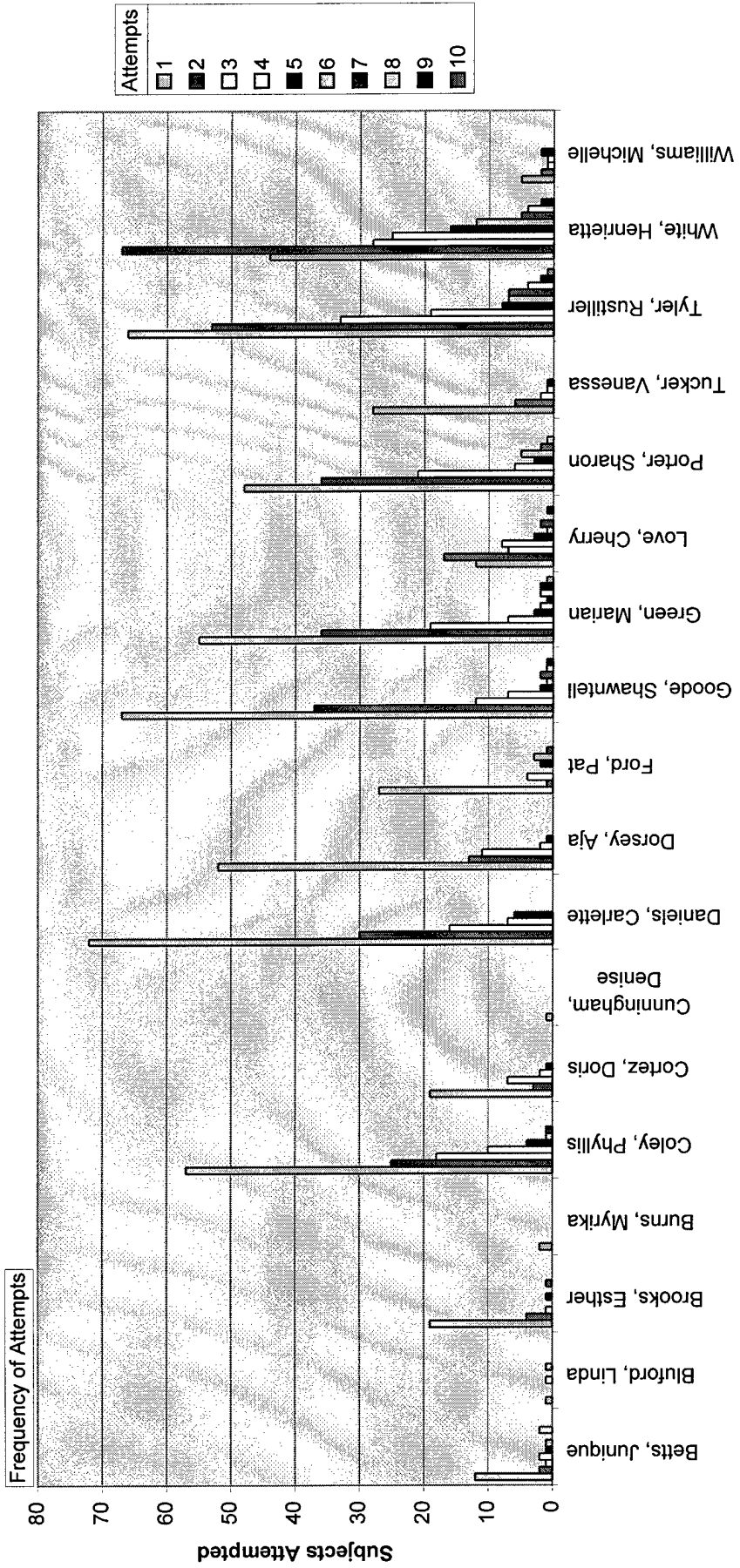


Weekday Afternoon Histogram



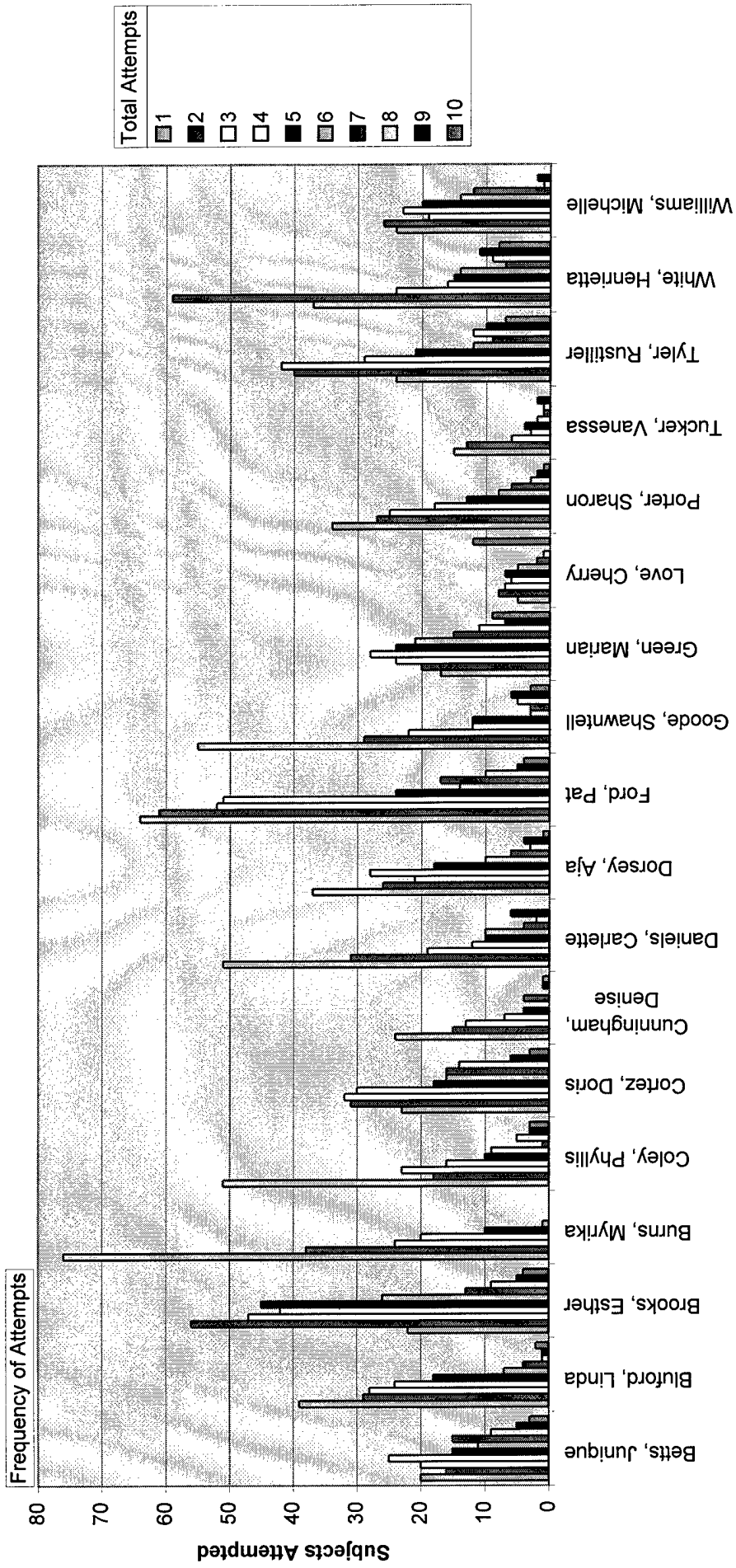
Recruiter

Weekday Evenings Histogram



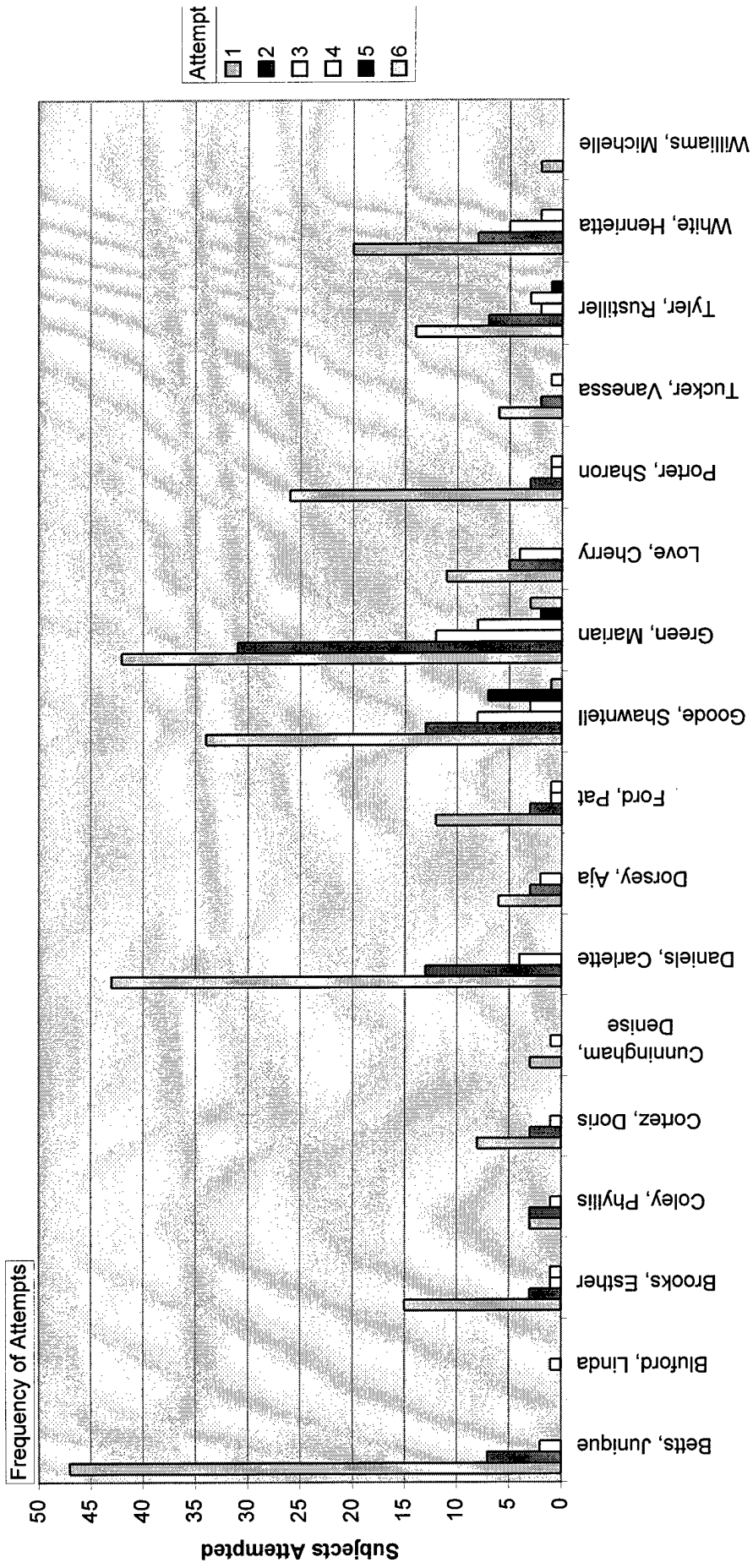
Recruiter

Total Attempts Histogram



Recruiter

Weekend Attempts Histogram



Recruiter

CATI

Week Ending:	31-Aug	07-Sep	14-Sep	21-Sep	28-Sep	05-Oct	12-Oct	19-Oct	26-Oct	02-Nov	09-Nov	16-Nov	30-Nov	07-Dec	14-Dec	21-Dec	28-Dec
Hours:				54.25	65.25	N/R	58.25	106.25	136.25	57.5	69	90	150.5	60.25	49.75	75.25	81
Weekly Completes:		9	12	11	17	13	16	40	50	15	31	26	57	36	19	39	15
Total CATI Completes:	398	407	419	430	447	460	476	516	566	581	612	638	695	731	750	789	804
Weekly Retrievals:		44	24	10	13	8	2	2	6	2	0	23	1	0	0	0	0
Total Retrievals:	129	173	197	207	220	228	230	232	238	240	240	263	264	264	264	264	264
Total Hours To Date:			3750.8	3805.0	3870.3	N/R	3928.5	4034.8	4171.0	4228.5	4297.5	4387.5	4538.0	4598.3	4648.0	4723.3	4804.3

CATI & hrs < 8/00 398 3750 4804 total hours

CATI & hrs > 8/00 407 1054

Call backs 264

hrs/CATI w callback & train 4.49

Hrs/Cati w training 2.59

Tracing Addresses and Phone Numbers

Week Ending:	31-Aug	07-Sep	14-Sep	21-Sep	28-Sep	05-Oct	12-Oct	19-Oct	26-Oct	02-Nov	09-Nov	16-Nov	30-Nov	07-Dec	14-Dec	21-Dec	28-Dec
Hours:				321	N/R	N/R	N/R	566	103	167.5	1050.5	648	316.50	138.5	142.00	162.5	0
Weekly Contacts:				50				187	45	70	115	75	81	44	23	68	
Total Contacts:			574	624	N/R	N/R	N/R	811	856	926	1041	1116	1197	1241	1264	1332	
Contact/Hour %								33%	44%	42%	11%	12%	26%	32%	16%	42%	
Total Hours To Date:			1046.3	1367.3	N/R	N/R	N/R	1933.3	2036.3	2203.8	3254.3	3902.3	4218.8	4357.3	4499.3	4661.8	

Traced >8/00 758

Hours >8/00 3615

Hrs/subject 4.77

Phone Recruitment

Week Ending:	31-Aug	07-Sep	14-Sep	21-Sep	28-Sep	05-Oct	12-Oct	19-Oct	26-Oct	02-Nov	09-Nov	16-Nov	30-Nov	07-Dec	14-Dec	21-Dec	28-Dec
Hours:				137.0	157.0	198.8	186.0	265.0	293.8	245.5	204.5	266.3	249.3	202.3	148.0	200.0	94.8
Consents Received:				22	33	10	24	45	31	18	19	33	66	21	49	44	32
Total Hrs	2848.02		16.11503														
Hr w/ Training	27801																
Total Consents	447																
Mean Rate/wk	30																
Cost/hour	16.12																
Mean Hrs/consent	9.2																
Projection w Top 4	4.4hrs/c or 647 hrs for 146 forms																
\$20,000/\$16.11	135 hrs will yeild 280 subjects																

Consent Form Staff	14-Sep	21-Sep	28-Sep	05-Oct	12-Oct	19-Oct	26-Oct	02-Nov	09-Nov	16-Nov	30-Nov	07-Dec	14-Dec Ratio *
Ford, Pat	32	30	36	33.5	36.5	34.5	32.5	8	32	27	5	367	55
Cortez, Doris	0	20.5	30	27	26.25	21	21.25	13.25	14	32	31	258	28
Cunningham, Denise	13.5	9.5	5	15.5	14.5	16.5	21.5	3.5				124	27
Green, Marian			16.52	16	16	16.5	13		16	16.25	16.5	127	27
Love, Cherry	15.5	22	23.75	23.5	27	22.25	18.75	9.75	3	11.5	14	234	20
Brooks, Esther	21.5	23	20.5	29	24.5	18	26.5	5	28	20.75	14.5	286	19
Porter, Sharon	11	9	14.5	15	14	14	19	4	14.75	11		141	15
Hampton, Mari-am	8.5	6.5	**	**	7		6		3			33	13
Dean, Shaurese	0	15.5	14.5	7.5	8	**	4					78	13
White, Henrietta								3	9	3	14	29	35
Coley, Phyllis	0	10.5	11.5	15	5		2					70	9
Thompson, Ericka			15	15	15	7.5	15		13	13.25		94	9
Williams, Michelle							8.5	15	20	19	14	77	7
Tyler, Rustiller			12.75	11	15.75	15	11	3	14	11.5	18	109	7
Goode, Shawntell	4.5	9.5	12	16.5	12	5	14	3	14	12		119	7
Brown, Louisa			14	9.5	13.25	9						46	6
Dorsey, Aja	5.5	5.25	10.5	13	6	10.75	12			14.75	20	91	6
Bluford, Linda							7.25	25	10	22		84	5
Spurlock, Reva			15		8.5							24	4
Cohn, Kathy	6.75	6.75	15.5	4.5	2	*						38	4
Brady, Elizabeth	20.75	8	*	*	*	*						29	3
Faison, Chantina	2.5	0	*	*	*	*						3	2
Daniels, Carlette									10		15	25	2
Stuart, Valerie			12	16	4.75	2.25	5		8	4.75	4	57	2
Betts, Junique								20.5	13	20	20.25	74	2
James, Charnita	0	0	*	*	*	*						0	1
Woodward, Lillian												0	1
Taylor, Delana			9.5	14.5	6.5	5	27		16	12	5	96	1
Oliver, Shawn				5	*	*						5	0
Miller, Nancy							7.75					8	0
Tucker, Vanessa			0	9.25	11	7.25	10	3			5	46	0
Burns, Myrika								14		15.5	20	50	0

Battelle tracked the number of hours it takes to conduct this study to date as it is very time consuming. In the two tables below, the total hours for each month for each task is presented to complete a CATI, trace a subject, and recruit the women by phone. The mean total for the number of hours per subject required to complete a CATI, trace a subject, and ascertain a consent form is 18 hours per subject: ~2.6 to 4.5 hours to complete a CATI, 4.8 hours to trace a subject, and 9.2 hours to obtain a consent form. The number of hours for a CATI could be reduced to 2.6 hours per subject if we eliminated the extra time needed to call back the initial set of subjects to obtain missing data.

Clearly the majority of effort is focused on obtaining consent. With 33 research assistants telephoning during the day and night, it takes a mean of 9.2 hours per subject to obtain a consent form and this amount of time is almost twice the time necessary to complete the other tasks. Therefore our costs are driven by this subtask and necessarily curtail our ability to complete the case control study.

8. Seek New Funding to Cover the Cost of Obtaining Informed Consent

In light of our financial short fall, our first alternative is to maintain a 1:1 ratio of controls for each case in order to at least finish two of the three adverse cases by interview. A second alternative is to seek additional sources of funding. To do this we are in the process of requesting extra funding to complete the original study from

- AFSMOA ~\$145,000 over two years: requested in July 2000
- US Army ~\$300,000 over two years; requested in October 2000
- CDC ~\$600,000 over two years; must submit by February 2001
- NIH ~\$953,000 over four years; must submit by February 2001

9. Design Tracing and Tracking Procedures

The subject tracing and tracking procedures are discussed and diagrammed in the AF Women Process Flow Charts located at the end of this section. The subject's status ranges from Tracing, Pre-Mailing, Mailing, Consents, Interviewing, Record keeping, Complete, or Dropped.

Tracing

The tracing process has three levels, (1) initial tracing, (2) intermediate tracing, and (3) advanced tracing. Our goal is to obtain the most accurate address to send the subject's information package. In the initial tracing stage, military data sets from the World Wide Locator (WWL) were considered the most accurate. If an address was found for a subject in WWL, we used this as the mailing address and the status is changed to Mailing. If no WWL information was available, we compared the Defense Manpower Data Center (DMDC) information with standard tracing databases including the National Change of Address (NCOA), TransUnion Credit Reporting (TU), and Telematch to obtain a set of names, addresses, and phone numbers for each subject. NCOA captures address changes with US Postal Service change of address cards filed by postal customers over the past three years. TU obtains addresses and phone numbers submitted to credit card companies, and Telematch is a computerized residential telephone number look-up service. Between these remaining data sets, we chose the mailing address of two of the most current addresses matched. If there were no matches, the subject was sent to intermediate tracing.

The intermediate tracing effort focused on a verbal confirmation of a correct mailing address using telephone number obtained in the initial tracing and supplemented with telephone search engines including CD-Rom based Phone Select, and Internet based locators switchboard, lookupusa, people,

and netcenter. The exchange is very minimal and involves the callers identifying themselves, asks if they may send the subject the packet, and confirms the mailing address; the subject's status is now Mailing. If all searches are exhausted without a confirmation, the subject is sent to advanced tracing.

The advanced tracing procedures add an additional step of obtaining a consent form.

Tracking

Once a reliable address has been obtained either through initial, intermediate, or advanced tracing, the subject is moved to the re-mailing stage. Because we are sending packages to Active Duty women at their base, we asked POCs to inform their Wing Commanders that the study is starting. The mailing is then clustered into a batch of Non-Active Duty and Active Duty with an approximate ratio of 1:2.

Using the tracking database, mailing dates, consent form status, and possible address/phone numbers obtained from tracing are entered in this database and are readily available to researchers.

The status of the subject is determined by the return of the subject package or contact with the subject. If both the informed consent document and medical record release forms are returned either by fax or mail and all signatures are complete (Consents status met), the subject's status will be moved to Interviewing. For review of the materials sent to the study participants, see the Study Population Package in Appendix C.

If there is no return of any materials one week after the mailing date or the returned material is incomplete, the Subject Coordinator will call them using the "Follow-up script". In the event the package has not been received by the respondent, the subject coordinator will verify the subjects mailing address and have Durham mail a second package to them. If the subject has the forms signed but have not returned them, the subject coordinator will facilitate their immediate return by fax or mail. In the event the forms have been returned either by fax or mail and are either incomplete or there are questions posed by the subjects, the interviewer will clarify any questions or, if necessary, have new forms sent by Durham/faxed directly by the subject coordinator. If the person does not want to participate, the subject coordinator will ask them to give their reason for refusal and ask to obtain basic job information from them over the phone. They will not be contacted again. The status of the subject will either be Mailing, Consents, or Dropped.

In the event the entire package is returned by the post office due to an incorrect address or forwarding information has expired, the subject is shuttled back to Tracing status into the next level of tracing (intermediate, advanced) by means of the tracking database.

INTERMEDIATE TRACING TELEPHONE SCRIPT

INTRODUCTION

Hello. My name is <Interviewer's Name>. May I speak with <First and Last Name of Mother> regarding her participation in an Air Force sponsored research study?

IF <First and Last Name of Mother> ISN'T HOME

When would be a good time for us to call back?

IF THEY KNOW

Date: _____ Time: _____

Can she be reached at this same telephone number?

[Verify telephone number.]

Phone number (if different) _____

Thank you, I will call her back on (date) at (time). Good bye.

[END CALL]

IF THEY DON'T KNOW

Can you please give her this toll free number (read number) so she can leave us a message arranging a time for us to call her back?

Thank you. Good bye.

[END CALL]

LEAVING MESSAGE ON AN ANSWERING MACHINE

Hello, this is <Interviewer's Name>. I am calling <First and Last Name of Mother> concerning an Air Force sponsored research study. Would you please have <First Name of Mother> call us collect at (PHONE NUMBER) and leave us a message arranging a time for us to call her back. Thank you. Good bye.

[END CALL]

WHEN PARTICIPANT IS ON THE PHONE:

Hello, My name is <Interviewer's Name> and I am calling regarding the Air Force study entitled "An Investigation of Reproductive Health and Potential Risk Factors among Active Duty Air Force Women".

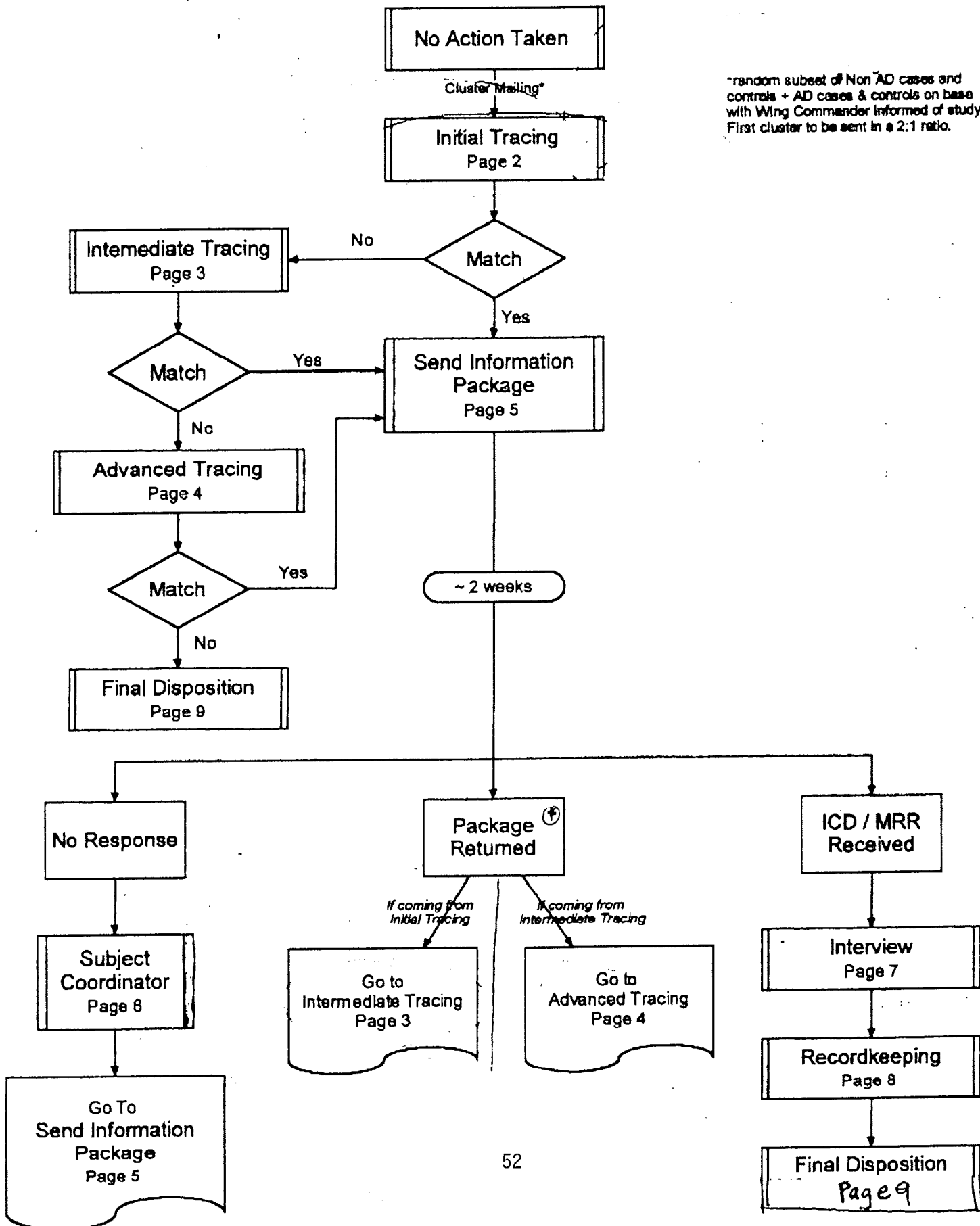
I would like to mail an information packet to you regarding this study. May I confirm your mailing address?

POTENTIAL SUBJECT ADDRESS	
FIRST NAME: _____	LAST NAME: _____
STREET: _____	
CITY, STATE: _____	ZIP: _____

Thank you. Either I or one of my colleagues will be calling to confirm that you received the packet and to answer any questions you may have. Is this the best telephone number and time of day where you can be reached? Verify Telephone Number

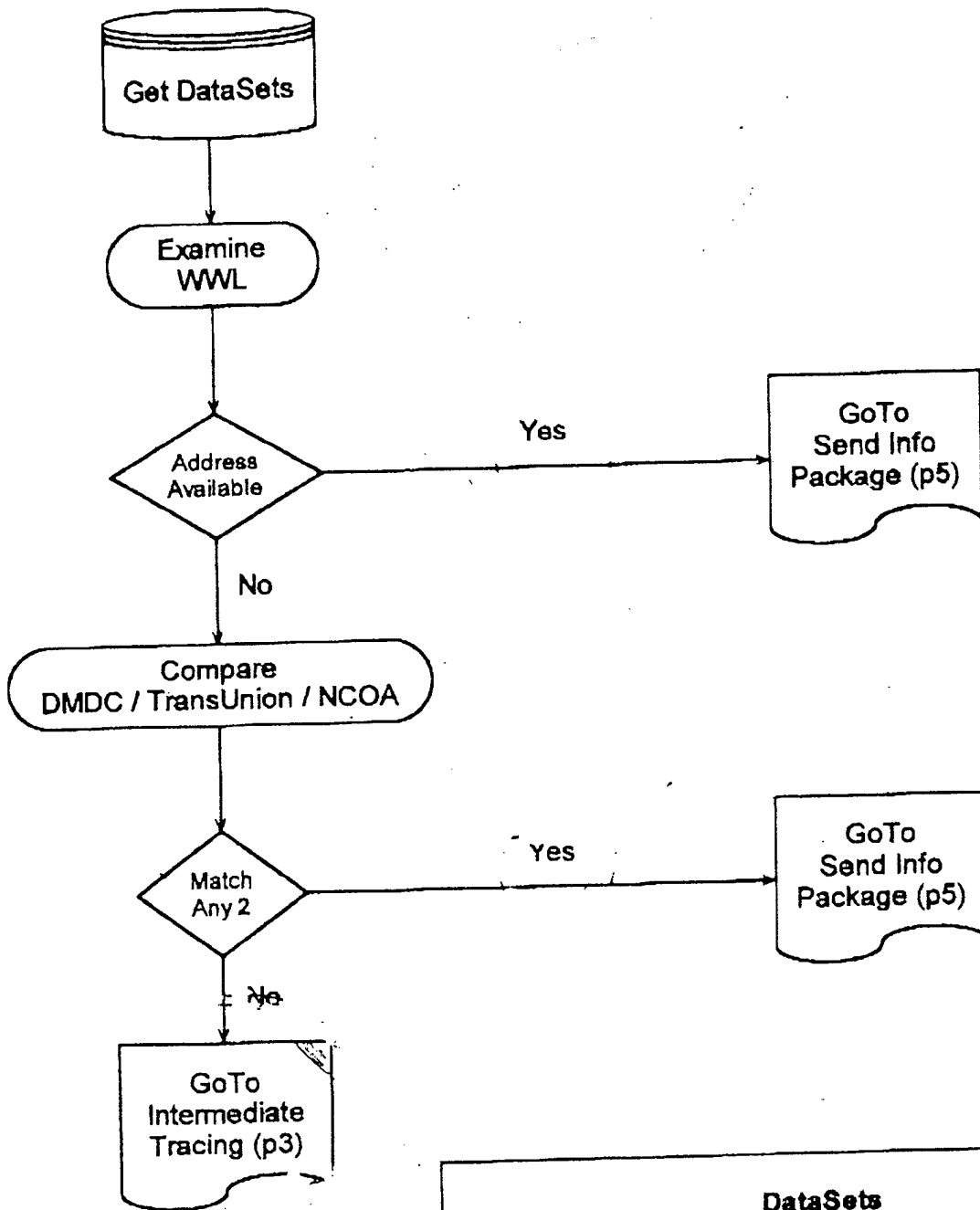
Phone Number _____

Air Force Women Process Flow Chart



random subset of Non AD cases and controls + AD cases & controls on base with Wing Commander informed of study. First cluster to be sent in a 2:1 ratio.

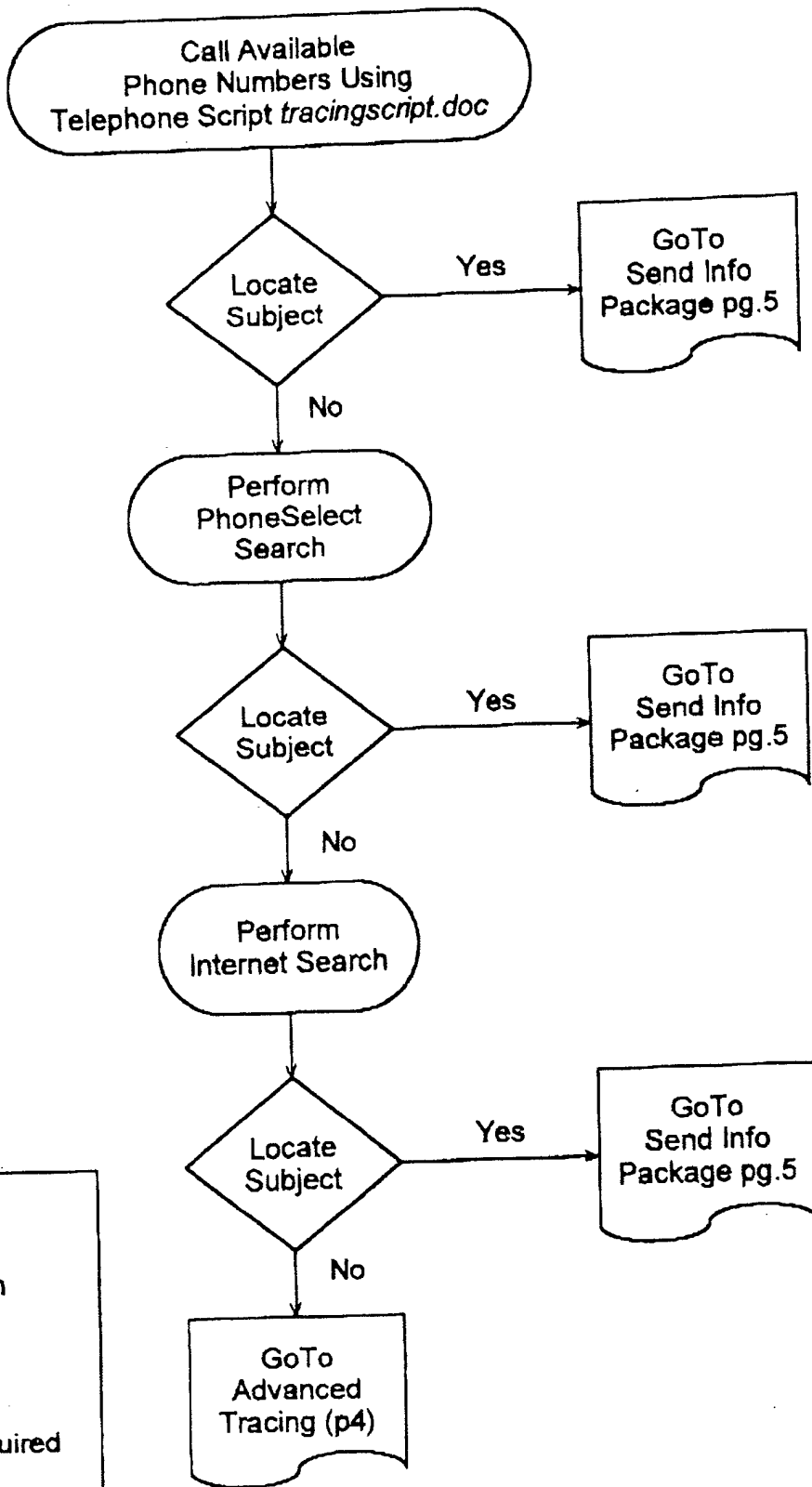
Air Force Women Initial Tracing Flow Chart



DataSets

- WWL - World Wide Locator (AD, retired, and reserve)
- DMDC - Defense Manpower Data Center
- NCOA - National Change of Address
- TransUnion Credit Reporting
- TeleMatch

Air Force Women Intermediate Tracing* Flow Chart (Durham)



Internet Locators
www.switchboard.com
www.lookupusa.com
people.yahoo.com
www.netcenter.com
 * - Verbal Verification Required

Air Force Women Advanced Tracing Flow Chart

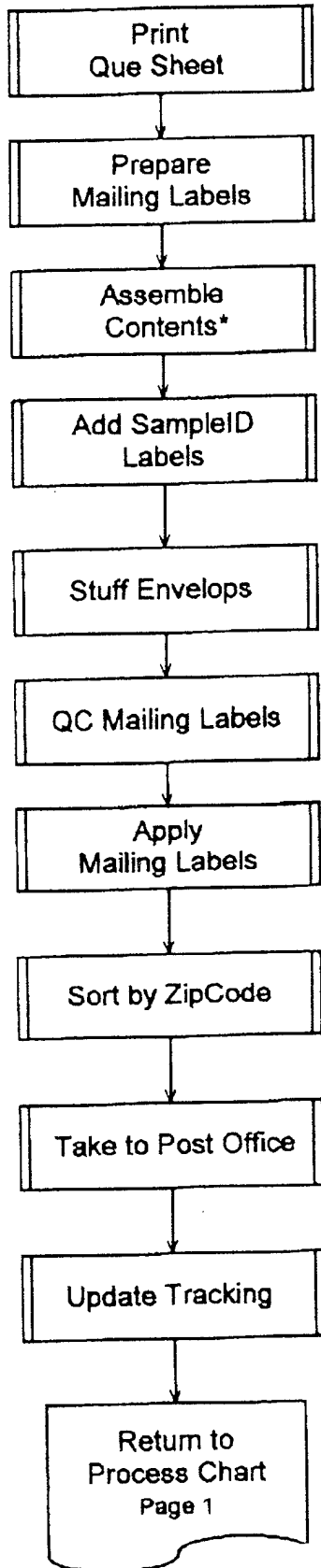
(St. Louis)

Under Construction

Cost and level of effort used to locate subject
will need to be determined by group.

Recommend waiting to see how many subjects fall into this category.

Air Force Women Send Information Package Flow Chart

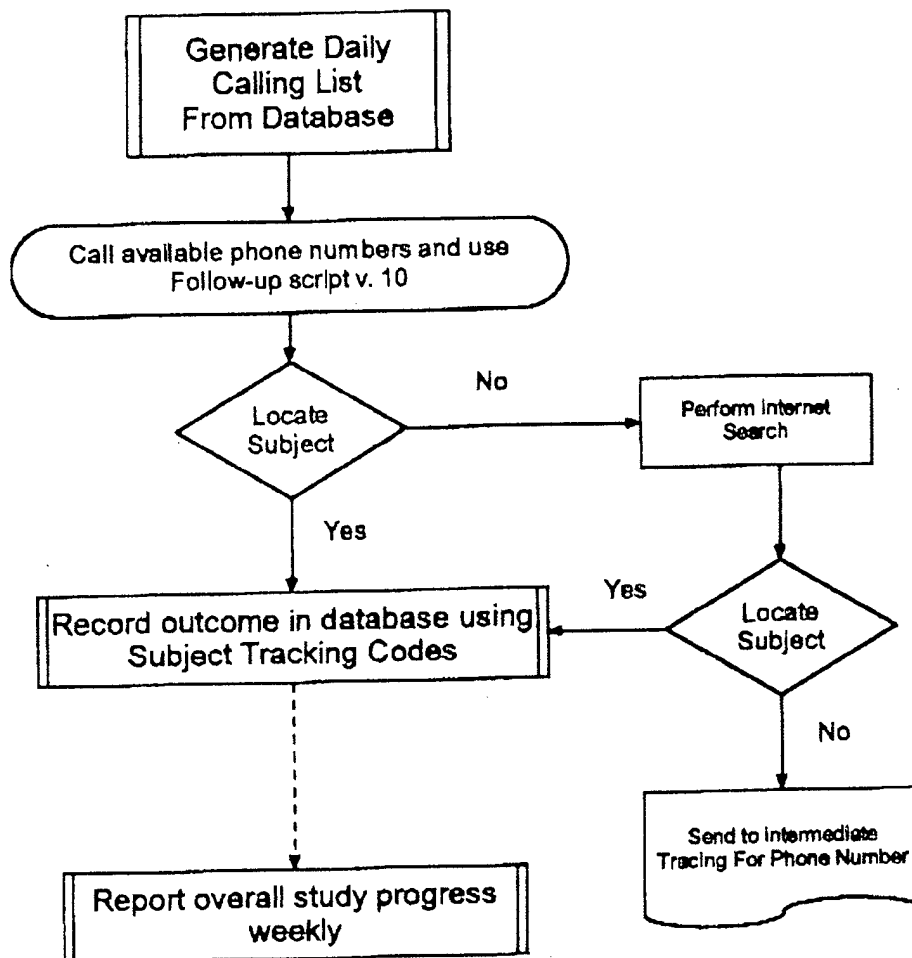


Envelope Contents
ICD
MRR
Participant Letter
Fax Cover Sheet
Cue Sheet*
Return Mail Envelope
Brochure

*Memory jogger. Gives study period dates; suggests having useful info such as vaccination records handy, etc.

Air Force Women Subject Coordinator Flow Chart

(Seattle/Vancouver)



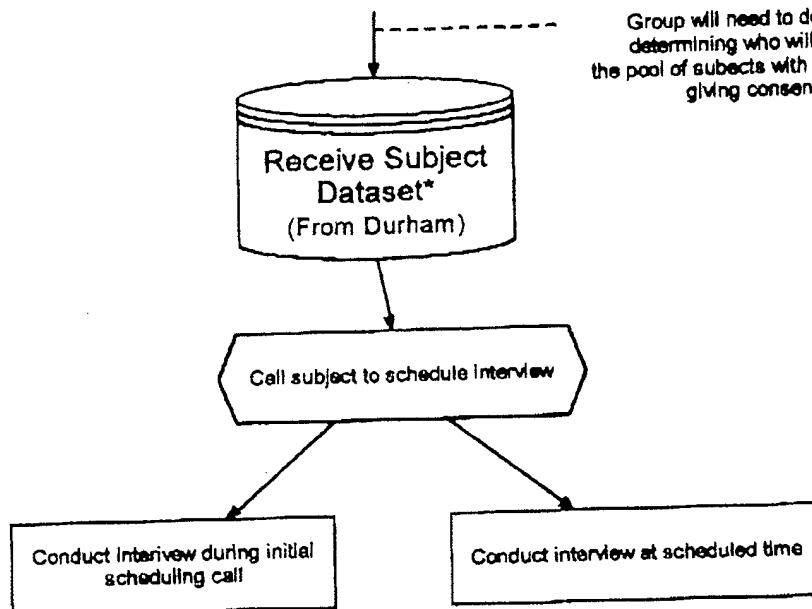
Subject tracking Codes

- Reschedule call-back time
- Update Telephone number
- Update Fax Number
- Durham needs to resend information package by fax
- Durham needs to resend information package by mail
- Verbal consent
- Indicated that they sent in MRR and ICD
- Refused to participate
- Refused by person other than participant
- Answer Machine (Message Left)
- Answer Machine (No Message Left)
- Sent to intermediate tracing to get phone number

Air Force Women Interviewing Flow Chart (St. Louis)

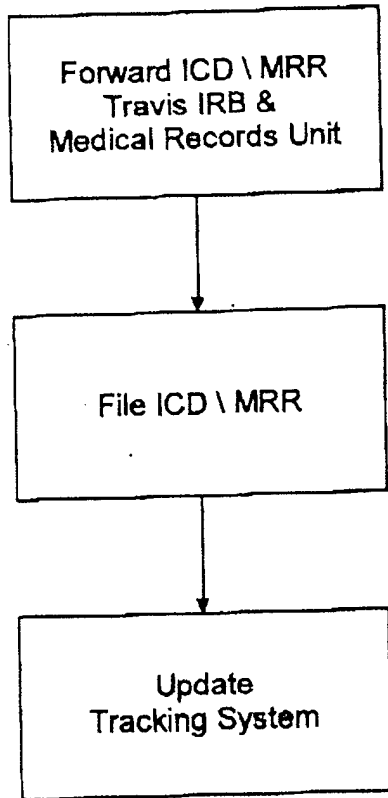
Target is 825 cases each of SA, PIHT
and PT (total cases = 1875). Number of
Controls is (18757).

Group will need to determine method for
determining who will be interviewed from
the pool of subjects with ICD/MRR returned to us
giving consent to participate

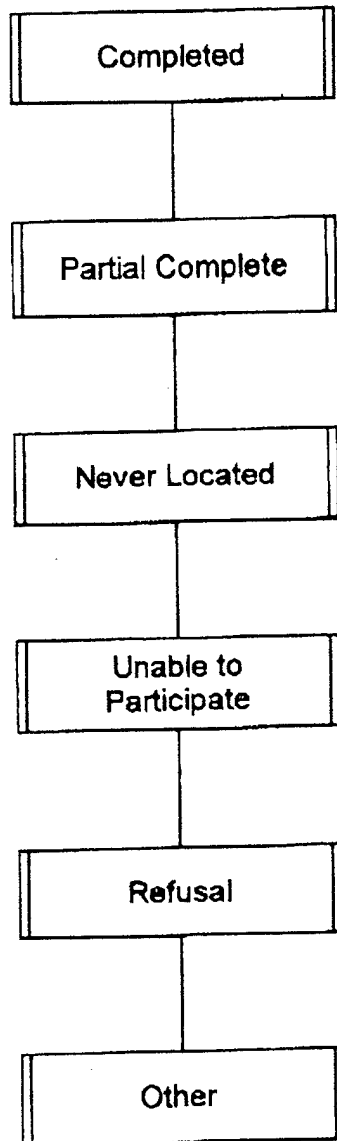


Air Force Women Recordkeeping Flow Chart

(Durham)



Air Force Women Final Dispositions



10. Data Collection and Analysis of the Case/Control Study

Data Collection

Battelle subcontracted with a mailing firm to mail out 2,000 letters per week during the month of February 2000 and again in February 2001. As of January 2001, we have received 1,045 consent forms. The final distribution of cases and controls is presented below.

There is a large pool of subjects who have said yes, but for whom we do not have a consent form. These subjects will be targeted first in January 2001. This will close out the normal group and permit us to focus on PT followed by SA.

The second large mailing included updated addresses and phone numbers for PT and SA. With a 33% return by mail we anticipate at least 200 consent forms for each outcome will be returned. The remaining ~200 consent forms per outcome will have to be obtained by phone calls.

At ~35 to 40 consents per week, this effort will take 10 more weeks.

	Accepted wo Consent	Remaining Pool	Accepted w Consent	CATI	CATI To Schedule	New CATI	Target
Normal	303	1953	482	378	104	148/303?	630
PT	92	633	208	166	42	422/92?	630
SA	121	607	205	150	55	425/121?	630
HT			150	111	34		

Data Analysis of the Case/Control Cohort

YR	Women	% Total	%Black	# Hisp	% HS
1990	7040	10.7	0.21	59	57
1991	6732	10.2	0.21	90	54
1992	7585	11.5	0.20	86	55
1993	5858	8.9	0.26	98	54
1994	7342	11.1	0.28	155	52
1995	7664	11.6	0.31	209	61
1996	8338	12.6	0.35	223	60
1997	8586	13.0	0.38	250	44
1998*	6879	10.4	0.37	165	39
Total	66024	100.0	0.29	1335	53

*1998 entering 01/98-09/98

ADAF Women Population

The cohort of 8,036 eligible ADAF women were selected from a background population of 66,024 active duty women described in Table 10-1.

Entry level distributions of all AF women by year, race, and percent with high school (across the years of the study period of 1990-1998) indicate that the proportion of Blacks has increased from 21% to 37% in the 9 year period while the number of Hispanics is far smaller.

In 1995, the midpoint of our sample, 22% of all ADAF women were Black and 24% of enlisted women were Black while 10% of officers were Black. Over the 1990-1998 study period, 55% of the population entered with a high school diploma and 25% entered with 1-6 years of college. The proportion

entering with just a high school diploma appears to be dropping in the last 2 years suggesting more women are entering with either a lower or higher education level. The mean age at entry into the AF was 20.6 (sd= 2.7) years old. Eleven percent of the entry population was 18-20 years old and 19% were older than 21 years old.

Preliminary Analyses of the ADAF Women Study Population, 1990-1998

Table 10-2 presents the distribution of demographic and SES indicators between cases (PT and PHT) and controls. The SES data were obtained by linking the potential subjects with AF personnel records (records on approximately 3000 additional ADAF women will be provided by the AF). Table 10-2 shows a broad distribution of demographic and SES variables (race, age, marital status, education, pay level), military variables (rank, years of service, region), and exposure variables (job group), allowing for each to be adequately addressed in the analyses without the need for stratification. The range of job groupings provides sufficient variation in exposure to physical work factors, hours of flight time, noise, heavy metals, and solvents, to examine statistically stable estimates of possible adverse effects related to these exposures. This is consistent with our stated hypotheses of evaluating social and occupational risk factors, and how they are impacted by parental and AF SES.

Additionally, most of these variables are disproportionately distributed between cases and controls, indicating that they are, in fact, potential risk factors for birth outcome. Major differences between cases and controls occur for race, age, highest educational level attained at the time of pregnancy, pay level, years of service (highly correlated to age), geographic region at time of pregnancy, and job title. Marital status also has some differences that do not meet the normal criteria of significance (<0.05 probability). Job title differences are particularly apparent for nursing. These patterns suggest that a number of important SES measures may be risk factors for adverse pregnancy outcomes.

Tables 10-3 and 10-4 further evaluate the associations between selected potential risk factors by presenting logistic regression models for each adverse pregnancy outcome individually. These models are based upon categorical data, with each baseline sub-category (odds ratio = 1) shown on the first line for each variable. Odds ratios for each of the other sub-categories are based upon comparison to the baseline sub-category for each variable. The largest sub-category for each variable was selected as the baseline category to provide the best stability for comparison, and equally important, to represent the "usual" or most common ADAF women characteristics.

Table 10-3 presents logistic regression models evaluating potential risk factors that primarily reflect conditions unrelated to the Air Force environment (representing personal rather than AF SES). For Pre-Term deliveries, race, age and marital status are all highly associated with the outcome. Education has only a borderline association. For Pregnancy Related Hypertension, it is noteworthy that age and marital status are not associated with the outcome, while the association with education becomes stronger. These considerable differences indicate distinct risk factors for these two adverse outcomes, providing a wider range for observing potential interactions with SES.

Table 10-4 presents similar logistic regression models in which the variable list has been expanded to evaluate potential risk factors directly related with the Air Force environment and especially with AF work. Education was omitted from this model because it was significantly correlated with pay level and is a determinant of job, both of which are dependent on SES.

For Pre-Term deliveries, race and age are again highly correlated with the outcome, with marital status also becoming an important association. Not shown, education had a borderline association ($p < .06$). In this analysis, nursing stands out as having the highest and most significant excess risk association

while other jobs appear protective. Note that the significant odds ratios for SES factors (race, pay level), age, and location, with control for exposure (where job title is a proxy) supports our new hypothesis that SES is a determinant of risk in conjunction with work exposure.

Pregnancy Related Hypertension presents a different profile. Age and marital status are not associated with this outcome, while the association with race and education is stronger. The most important association with job for this outcome is with medical technicians/administration. Given that the odds are significant in health care for both outcomes suggest that exposures among these workers might represent a true and potentially serious risk.

Table 10-2: Distribution of SES & Demographic Factors among ADAF Cases & Controls

MEASURE	SUB-GROUP	% CONTROL N=	% CASE N=	% TOTAL N=5103	PEARSON CHI2	p
Race	White	73.76	68.09	71.94	26.21	0.00
	Black	19.23	25.50	21.24		
	Other	7.02	6.41	6.82		
Age	<20	8.00	10.37	8.76	11.84	0.01
	21-25	46.13	45.09	45.80		
	26-30	30.43	27.64	29.53		
	>30	15.44	16.90	15.91		
Marital Stat	Single	7.91	8.91	8.23	5.40	0.07
	Married	83.23	83.95	83.46		
	Div/Sep	8.86	7.14	8.31		
Entry Edu	Low	82.69	81.88	82.43	0.50	0.78
	Medium	14.00	14.66	14.21		
	High	3.31	3.46	3.36		
Final Edu	Low	45.26	48.14	46.19	7.62	0.02
	Medium	39.34	35.33	38.05		
	High	15.40	16.53	15.76		
Pay Level	E1-E4	53.81	59.00	55.48	21.76	0.00
	E5-E9	33.20	26.72	31.12		
	Officer	12.99	14.28	13.40		
Rank	Enlisted	87.01	85.72	86.60	1.59	0.21
	Officer	12.99	14.28	13.40		
	Yrs Service	<2yrs	11.14	14.47		
Region	2-3yrs	28.61	30.95	29.36	20.31	0.00
	4-5yrs	22.03	21.49	21.85		
	>5yrs	38.22	33.09	36.57		
	ConUS	87.73	91.58	88.97		
Job Group	Europe	4.50	3.60	4.21	18.16	0.00
	Asia	7.77	4.82	6.82		
	Logis-Maint	7.32	5.96	6.88		
Job Group	Logis-Admin	13.24	14.12	13.52	53.08	0.00
	Clinical	1.54	1.82	1.63		
	Nursing	11.08	15.81	12.60		
	Rad-Lab-DDS	4.53	4.27	4.45		
	Ele Eng-PhD	3.94	4.02	3.96		
	Med-Admin	5.36	7.09	5.92		
	Flight	1.04	0.38	0.83		
	Intel-Traff	4.47	3.26	4.09		
	Ops-Admin	2.28	2.45	2.33		
	Security	5.30	4.77	5.13		
	Civil Eng	1.51	0.63	1.23		
	Avionics	5.48	3.76	4.93		
	Supply-Admin	32.89	31.68	32.50		

TABLE 10-3 SES Prior to Air Force Enlistment for Normal Vs. Adverse Outcomes

Variable	df	PRE-TERM DEVLIVERY				HYPERTENSION			
		B	S.E.	Sig	OR	B	S.E.	Sig	OR
Black (v White/Other)	1	.45	.09	.00	1.66	.30	.10	.00	1.35
Age Group (v Age 21-30)	2			.01				.41	
AGE <21	1	.33	.13	.01	1.39	.19	.14	.19	1.21
AGE >30	1	.23	.11	.03	1.25	-.03	.13	.81	.97
Single (v Married)	1	-.25	.11	.02	.78	.03	.11	.79	1.03
Education Group (v Low)	2			.06				.04	
Medium	1	-.21	.09	.05	.90	-.24	.09	.01	.79
High	1	.14	.12	.23	1.15	-.15	.14	.26	.86
Constant	1	-1.43	.07	.00		1.56	.07	.00	

TABLE 10-4 SES Prior to Air Force Enlistment, AF SES for Normal Vs. Adverse Outcomes

Variable	df	PRE-TERM DEVLIVERY				HYPERTENSION			
		B	S.E.	Sig	OR	B	S.E.	Sig	OR
Black (v White/Other)	1	.46	.09	.00	1.58	.28	.10	.01	1.32
Age Group (v Age 21-30)	2			.00				.48	
AGE <21	1	.28	.13	.04	1.32	.12	.15	.42	1.12
AGE >30	1	.32	.11	.01	1.38	.13	.14	.36	1.14
Single (v Married)	1	-.24	.11	.03	.79	.01	.11	.90	1.01
Pay Group (v E1-4)	2			.03				.00	
E5-9	1	-.25	.09	.01	.78	-.51	.11	.00	.60
O1-6	1	-.14	.15	.34	.87	-.25	.17	.14	.78
Geography (v CONUS)	2			.02				.00	
Europe	1	.02	.19	.90	1.02	-.60	.26	.02	.55
Pacific	1	-.48	.17	.00	.62	-.52	.19	.01	.59
Job Group (v Supp-Admin)	13			.00				.03	
Logistics-Maint.	1	-.10	.17	.54	.90	-.12	.18	.51	.89
Logistics-Admin.	1	.07	.12	.60	1.07	.13	.13	.32	1.14
Clinical	1	.45	.30	.13	1.57	-.20	.42	.63	.82
Nursing	1	.55	.12	.00	1.74	.11	.15	.46	1.12
Radiation-Lab-DDS	1	-.16	.20	.44	.85	.03	.20	.89	1.03
Envir.Eng.-PhD	1	-.04	.22	.86	.96	.18	.22	.40	1.20
Medical-Admin.	1	.20	.17	.24	1.22	.37	.17	.03	1.45
Flight	1	-.79	.54	.14	.46	-1.26	.73	.09	.28
Intel-Traffic Cntl.	1	-.50	.24	.04	.61	.05	.22	.83	1.05
Operations-Admin.	1	.17	.25	.49	1.19	.02	.29	.94	1.02
Security	1	-.27	.20	.17	.76	.06	.19	.75	1.06
Civil Eng.	1	-.80	.44	.07	.45	-.97	.53	.07	.38
Avionics	1	-.08	.19	.68	.93	-.73	.26	.00	.48
Constant	1	-1.39	.09	.00		-1.46	.09	.00	

Table 10-5 The percent of women with the most frequently reported exposures: noise, metals, and solvents

AFB, Tot.	Noise	Lead	Solvents	Jet Fuel
Hill, n=13,275	N=4,673, 35%	N= 912, 7%	N= 2,716, 20%	N= 738, 6%
McChord, n=2,206	N= 610, 28%	N= 54, 2%	N = 250, 11%	N= 571, 26%
Lakeland, n=18,750	N= 6,045, 32%	N= 2,154, 5%	N= 2625, 14%	N=3,375, 18%

Source: Industrial Hygiene, Hill Air Force Base, Utah (1999); Job Title Source: Armstrong Laboratory Human Resources Directorate; extracted from the Uniform Airman Record and the Uniform Officer Record (June, 1993).

Distribution of Selected Occupational Exposures

Our occupationally-relevant results are necessarily limited because job title is a proxy for specific exposures currently being collected on the CATI, and may introduce misclassification. For example, the proportion of women exposed to selected occupational agents varies by the type of AF command and job title.

Table 10-5 presents some of the expected variation in exposure depending on whether the AF base is in the Materiel (McChord), Operational/depot maintenance (Hill), or Training (Lakeland) Command. In general, noise is the most prevalent exposure, followed by jet fuels, other solvents, and metals. Associated with these exposures are a broad range of non-traditional jobs held by members of the cohort that supports the premise that women in the AF are broadly exposed as compared to civilians, increasing the sensitivity of the study to detect associations with adverse outcomes. As described in Section D8.2, there is adequate statistical power (with an $\alpha = .05$, $\beta = .80$) to detect a minimum change of 5% for all agents.

Conclusions

The preliminary results mark a study in process that would be significantly strengthened by completing the case-control study. The results do demonstrate that ADAF women are an ideal population in which to assess the impact of parental SES and personal SES factors on birth outcomes with respect to a wide range of exposure risk factors. ADAF women have standardized access to health care and little confounding prior occupational experience. However, to meet these goals, it is necessary to 1) define specific exposures, 2) define confounding factors such as smoking, health, and other lifestyle choices, and 3) define the range of parental and personal SES component variables, and 4) verify the quality of data, prior to developing firm conclusions regarding risk factors.

Understanding the role of parents' and personal SES for PT and PIHT will permit a more meaningful and complete context for interpretation of findings. Our research evaluates, for the first time, the extent to which adverse pregnancy outcomes are rooted in intergenerational social and economic processes. The addition of indicators of parental SES and the potential attenuating effect of social capital on adverse pregnancy outcomes significantly enhance these analyses. The addition of operational factors (e.g., deployment, forced separation, and relocation) are also of research interest to the AF and their inclusion in the study is consistent with examining psychosocial stressors. Our methods rely on the CATI verified with historical information abstracted from the various AF records. Methodologically, the AF SIDR data, BEE record, and the CATI data will be rigorously compared through abstraction of AF exposure and medical records resulting in estimates of recall bias. Verified exposure assessments corrected for potential recall bias are a unique strength of this study.

The proposed analyses will permit far more specific insights into the etiology of PHIT and PT, helping identify where future interventions would be most valuable. Personal risk factors collected on the CATI (e.g., smoking, alcohol and drug consumption, compliance with weight allowances, injury, and domestic violence) may also suggest remedial behaviors that the AF can target for future interventions

Public Health Significance

Evaluating risk factors associated with disparities in adverse reproductive health in a military population will significantly clarify the contribution of variation in SES and occupational exposures, minimizing the immediate effects of uneven access to health care. One of our study hypothesis is to evaluate pre-enlistment parents' SES in addition to current personal SES and social capital in order to determine for the first time the extent to which inequalities in adverse pregnancy outcomes are rooted in

intergenerational processes. The study fills a gap in investigations of family of origin effects on SA, PT, and PIHT and expands our understanding of intergenerational influences on health. Importantly, we will test the process through which parental SES and social capital leads to adverse health outcomes by testing its effects on job entry and occupational exposures in the AF. The AF will benefit by understanding how their comprehensive health benefits interact with the influence of SES. As obstetrics accounts for the highest health care cost in the AF, increased knowledge of reproductive risk factors for the full range of low to high SES women will improve future interventions, health care planning, and health promotion in the AF.

APPENDIX A

Data Dictionary

Air Force Women Reproductive Outcomes Study
Data Dictionary
Version 6
(as of 02/09/2000)

Coding

DATASOURCES

0	Unknown
1	SIDR
2	CRDB
3	DMDC
4	TransUnion
5	NCOA
6	Worldwide Locator
7	Pentagon
8	Tele-I-Match
9	Subject
10	Postal Service

ICD9-CM CODES

642	Pregnancy Induced Hypertension
634	Spontaneous Abortion
644	Pre-Term Delivery
650	Normal Delivery

STUDY STATUS

0	Dropped
1	Tracing
2	Mailing
3	Consents
4	Interviewing
5	Recordkeeping
6	Complete

DUTY STATUS

1	Active Service
2	Overseas
4	Separated
5	Retired
6	Deceased
7	Can Not Identify
8	Protected Airmen
9	Other Branch of Service
10	Deserted
11	Unknown
12	No Record

ADDRESS STATUS

1	Valid Primary (Verified)
2	Valid Secondary (Verified)
3	Active
4	No Action Taken
5	Rejected

ADDRESS CODES

0	No Action Taken
1	Work
2	Home
3	Other Address
4	Incomplete
5	Invalid

PHONE STATUS

1	Contacted
2	Active
3	No Action Taking
4	Invalid

PHONE CODES

0	No Action Taken
1	Valid
2	Active – No Answer
3	Active – Left Person Message
4	Active – Left Machine Message
5	Active – Other
6	Invalid - Fax/Computer Line
7	Invalid - Trouble on Line
8	Invalid - Not in Service
9	Invalid – Timed Out
10	Invalid - Other

FOLLOW-UP CODES

0	No Action Taken
1	Actively Calling
2	Contacted - Incomplete
3	Contacted – Accepted
4	Contacted – Maybe
5	Contacted – Soft Refusal
6	Contacted – Hard Refusal
7	Timed Out

Data Structure

Database: AFTracking.mdb

Table Name: tbl_Address

Name	Type	Size	Comments
SubjectID	Text	7	
SourceDATE	Text	4	
AddPriority	Number (Integer)	2	
Address1	Text	150	
Address2	Text	150	
Address3	Text	150	
CITY	Text	50	
STATE	Text	10	
ZipCode	Text	10	
AddRecNum	Text	255	
AddCode	Number (Integer)	2	
AddStatus	Number (Integer)	2	

Table Name: tbl_Phone

Name	Type	Size	Comments
SubjectID	Text	7	
CITY	Text	30	
STATE	Text	2	
AreaCode	Text	3	
LocalPhone	Text	8	
PhoStatus	Number (Integer)	2	
PhoCode	Number (Integer)	2	
PhoPriority	Number (Integer)	2	
SourceDATE	Text	4	
PhoneRecNum	Text	7	

Table Name: tbl_Subjects

Name	Type	Size	Comments
SubjectID	Text	7	
SSN	Text	9	
StudyStatus	Number (Integer)	2	
DutyStatus	Number (Integer)	2	
DropStatus	Number (Integer)	2	
TraceStatus	Number (Integer)	2	
MailStatus	Number (Integer)	2	
BatchNum	Number (Integer)	2	
DocStatus	Number (Integer)	2	
InterviewStatus	Number (Integer)	2	
Rank	Text	5	
FName	Text	30	
MName	Text	30	
LName	Text	30	
AKA	Text	30	
SubjectDOB	Date/Time	8	
Address1	Text	255	
Address2	Text	255	
Address3	Text	255	
CITY	Text	100	
STATE	Text	10	
ZipCode	Text	10	
CurDutyBase	Text	50	
PhoWork	Text	12	

Table Name: tbl_Subjects (con't)

Name	Type	Size	Comments
PhoHome	Text	12	
Fax	Text	12	
MailDate	Date/Time	8	
FollowUpDate	Date/Time	8	
Consent	Yes/No	1	
MedRelease	Yes/No	1	
MedRecords	Yes/No	1	
TransmitDate	Date/Time	8	
InterviewDate	Date/Time	8	
CompleteDate	Date/Time	8	
PhoRecNum	Text	7	
AddRecNum	Text	7	
AdmDate	Date/Time	8	
TARGDXShort	Text	3	
EventDutyBase	Text	50	
EventDutyZip	Text	5	
AdmYYMM	Text	4	
AFSC1Short	Text	7	
AFSC_Title	Text	255	
AFSC1	Text	7	
AFSC2	Text	7	
AFSC3	Text	7	
eMail	Text	35	
Loaded	Yes/No	1	

Data Sources

Military Databases

natality.crdbdxprtran1.sd2
natality.crdbdxprtran2.sd2
natality.sidr.sd2
natality.xport.dt.sd2
dmdc_contact.xls
dmdc_demo.xls
wwl1222TableA.DOC
wwl1222TableB.DOC

Civilian Databases

transunion.dbf
ncoa_rtrns.dbf

AFWomen Databases

AFWomen.mdb
AFTracking.mdb

Battelle Databases

HRRD BATV1
SIDR BATV1

APPENDIX B

Study Population Package

INFORMED CONSENT DOCUMENT

60TH MEDICAL GROUP
David Grant Medical Center
101 Bodin Circle
Travis AFB, CA 94535-1800

Privacy Act of 1974 applies. DD Form 2005 filed in Clinical/ Medical Records.

PRIVACY ISSUES: Records of my participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 USC 552a, and its implementing regulations. DD Form 2005 contains the Privacy Act Statement for the records. I understand that the U.S. Food and Drug Administration (FDA), the sponsoring agency and/or their designee may inspect records of this study, if applicable.

TITLE OF STUDY

"An Investigation of Reproductive Health and Potential Risk Factors among Active Duty Air Force Women"

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

Principal Investigator	Diana Echeverria, Ph.D.	206-528-3131	Battelle, Seattle, WA
Co-Investigator	John Herbold, Ph.D.	210-567-5930	University of Texas, Houston
Co-Investigator	Lt.Col. Kevin Grayson	707-424-6535	U.S. Air Force, Travis AFB
Co-Investigator	Lowell Sever Ph.D.	206-528-3348	Battelle, Seattle, WA
Project Contact	Nicholas Heyer, Ph.D.	206-528-3224	Consultant, Seattle, WA
Human Subject Comm.	Margaret Pennybacker, PhD	919-544-6587	Battelle, Durham, NC

INTRODUCTION

It is important that I read and understand several general principles that apply to all who take part in research studies: (a) taking part in the study is entirely voluntary; (b) personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others; (c) I may withdraw from the study at any time without penalty or loss of any benefits to which I am otherwise entitled.

PURPOSE OF STUDY

(This section will explain the nature, purpose(s), approximate number of subjects, and the duration of participants' involvement.)

I, _____ (SSN: _____), understand that I am being asked to participate in the only study of pregnancy, miscarriage, and births currently being conducted among former and current active duty Air Force women. The Air Force has an excellent track record of supporting active duty women who become pregnant. Since 1975 it has allowed women who become pregnant to remain on active duty. This may partly explain why the Air Force has the highest reenlistment rate among active duty women in all branches of the US military. Earlier studies have shown that birth rates among active duty-Air Force women generally exceed those of the US working population. Air Force women also have better pregnancy outcomes, reflecting their good health, excellent health benefits, and the safety of Air Force workplaces. Nevertheless, it is possible that Air Force work environments may have influenced unsatisfactory pregnancy outcomes on active duty women. I understand that this study intends to investigate these connections with the hope of preventing unsatisfactory pregnancy outcomes among active duty Air Force women in the future.

I understand that this study will evaluate possible associations between three pregnancy outcomes; high blood pressure during pregnancy, miscarriage, early delivery, and a broad range of personal and work-related factors previously suspected of being associated with these outcomes. I have been randomly selected for this study because my hospital records indicate my experience with one of these outcomes, or I had a completely normal delivery between 1990 and 1998. If I decide to participate, I understand that a collection of information will be requested from my work history and military records data, and also, a telephone interview will be required.

PROCEDURES

(This section will explain all procedures and the purpose of the procedures to be undergone as part of this study. Any experimental procedures will be explained as such.)

The study will be conducted over a two-year period and will include approximately 1,900 pregnancies with one of the three outcomes being studied, and an additional 1,900 pregnancies without any complication for comparison. If I decide to participate, the following is required:

- 1) written permission to use my pregnancy-related Air Force inpatient and outpatient medical records, and
- 2) written permission to schedule me for a telephone interview to be conducted at my convenience.

The telephone interview, which will take an hour or less, will collect information on:

- my work history over a period starting three months prior to conception and continuing until the end of that pregnancy
- a review of chemicals (including solvents, metals, pesticides, etc.) and other factors (including level of physical activity, stress, noise, vibration, etc.) I may have encountered in my workplace during my pregnancy
- a brief medical history with associated medications
- a reproductive history including voluntary abortions
- personal habits including smoking and alcohol consumption for each pregnancy

BENEFITS

I understand that no benefit can be guaranteed. I understand I will not receive payment for participating in this study, and I may not directly benefit from its findings. It is hoped that this study will establish a better understanding of the relationships between personal characteristics, Air Force workplaces, and pregnancy among active duty Air Force women.

ALTERNATIVES

(This section will explain your alternative treatment possibilities)

The alternative is not to participate in this study.

RISKS/INCONVENIENCES

(Any discomfort, risks, and inconveniences caused from procedures or drugs used that may be expected from participation in this study.)

I understand that the only risk from my participation in this study is the possible loss of privacy and confidentiality. While it is possible that my personal and medical information could be unintentionally released, the investigator for this study will be taking stringent precautions to avoid this. First, the investigators will remove my name and Social Security Number from all of my files and store them separately. Codes, known only to the research team, will be used to identify my records. Second, all the data will be stored in a secured area with access limited to the investigators. My name will never appear on any reports and only summary information will be published. The information collected for this study will be kept secure and maintained for five years from the completion of the study. At that time, it will be destroyed.

DECISION TO PARTICIPATE

The decision to participate in this study is completely voluntary on my part. No one has coerced or intimidated me into participating in this program. I am participating because I want to. The study investigator(s) has adequately answered any and all questions I have about this study, my participation, and the procedures involved. I understand that the investigators will be available to answer any questions concerning the procedures throughout this study. I understand that if significant new findings develop during the course of this study that may relate to my decision to continue participation, I will be informed. I further understand that I may withdraw this consent at any time and discontinue further participation in this study without prejudice to my entitlement to care. I will be provided with a copy of this consent form.

I understand that I may refuse to participate in all or any part of this study, or refuse to answer any specific question without penalty. All information obtained about me, as an individual will be considered privileged and held in strict confidence. My identity will remain private. I will not be identified in any presentation of the results. No individual data about me will be released; only summary data will be published.

If I decide to participate, I will read and sign the signature page of this informed consent document, as well as the attached medical records release form.

1. I have read this informed consent document and understand the purpose and benefits, procedures, and risks associated with my participation in the study.
2. I agree to participate in the study. I understand that my participation is voluntary and that I may decide not to participate in any or all portions of this study at any time without penalty; and that I may decide not to answer any particular question or part of a question.
3. I give permission to allow the study researchers to schedule a one-hour interview at my convenience.

If I decide to participate I will be contacted in the next few weeks to schedule a convenient time for the telephone interview. Otherwise, if I decide not to participate, I will not be contacted again.

4. I may also give written permission to use my pregnancy related USAF inpatient and outpatient medical records using the attached "Medical Record Release Form". I understand that the information obtained from my medical records will be limited to my pregnancy and these and my telephone interview will remain strictly confidential.
5. I understand that my name will never appear on any reports; and that only summary data from the study will be published.
6. I understand that this study is in compliance with standards for treatment of human subjects by our various research institutions and the US Air Force.
7. I understand this investigation is a Defense Advisory Committee on Women in the Services (DACOWITS) study. It should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research.

8. I understand copies of an Executive Summary of this study can be obtained by requesting a copy from the following address:

Air Force Women's Health Study
 Battelle CPHRE, 100 Capitola Drive, Suite 301
 Durham, NC 27713-4411

or by calling (919) 544-3717 and asking for the Air Force Women's Health Study representative.

My signature below indicates my willingness to participate in this research study.

 (Subject's Printed Name)

 (Subject's SSN)

 (Subject's Signature)

 (Best commercial phone number to reach you)

 (Date)

INSTRUCTIONS

Informed consent document (4 pages)

- Fill in name and social security number in Purpose of Study section of page 1.
- Initial each page at the bottom right corner.
- Complete the section above, including your signature indicating your willingness to participate in the study.

Medical records release form (1 page) attached

- Complete form including location of Medical treatment facility where treated or delivered and the location of your medical records.

The signed forms (5 pages total) should be either mailed in the enclosed envelope or faxed with the enclosed fax cover sheet to Mr. Stephen Wilkins at (919) 544-0830. An additional copy of each form is provided for your records.

And finally, to aid us in the collection of the workplace Industrial Hygiene casefiles, please complete the following information about your workplace during the study period defined on the Que Sheet:

Job Title _____ AFSC _____ Base Assigned _____

Organization _____ Office symbol _____ Duty section _____

Briefly describe your immediate workplace:

MEDICAL RECORD RELEASE FORM

I give my consent for the _____
(Name of Medical Treatment Facility where you were treated or delivered)

and the _____
(Name of Medical Treatment Facility where your outpatient medical records are currently located)

to provide my pregnancy related USAF inpatient and outpatient medical records to members of the *Investigation of Reproductive Health and Potential Risk Factors Among Active Duty Air Force Women* research staff. The medical information that is collected will only be used for research purposes by the research staff and that the information obtained will remain confidential.

Signature: _____

Printed name: _____

Social security number: _____

Date: ___/___/___

This consent is effective upon signing and shall remain valid until September 30, 2000 or until the end of the study, whichever occurs first.

How can I help?

1. Read the enclosed literature. The information provided describes the background and goals of the study in detail.
2. Sign the enclosed INFORMATION SHEET and MEDICAL RECORD RELEASE forms.
3. Send the INFORMATION SHEET and MEDICAL RECORD RELEASE forms by fax to Mr. Stephen Wilkins (919) 544-0830; or use the enclosed self-addressed envelope provided. Faxing is preferred.

Then what?

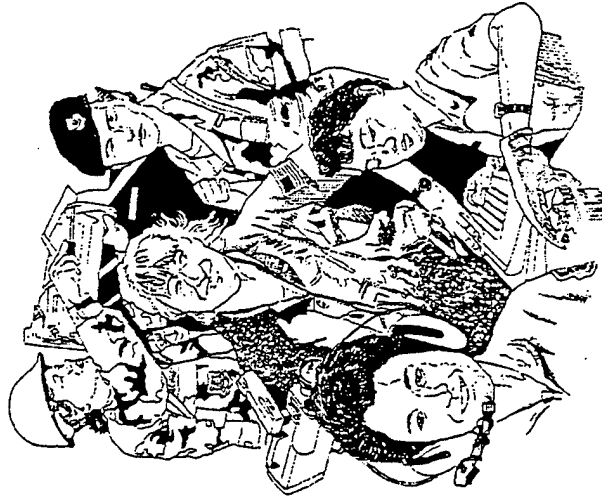
When we receive your forms, we will contact you to schedule a telephone interview at your convenience. The interview will be your only time commitment.

We will also collect work history and pregnancy data from your military records. We will only need information about your pregnancy, and we will not need to contact you for this information.

All information obtained about you will be considered privileged and held in strict confidence.



Air Force Women Focus of Pregnancy Study.....



THE UNIVERSITY OF TEXAS - HOUSTON
HEALTH SCIENCE CENTER



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Battelle Centers for Public Health Research and Evaluation
100 Capitola Dr. Suite 301
Durham, NC 27713-4411

(919) 544-3717
Fax (919) 544-0830

Here's your chance to make
a contribution toward
improving pregnancy
outcomes for all women

"An Investigation of Reproductive Health and Potential Risk Factors Among ADAF Women"

WHAT IS THIS STUDY ALL ABOUT?

You are among 4000 randomly selected former and current active duty Air Force women selected for participation in a study investigating women's reproductive health. We will be evaluating factors related to the occurrence of four different pregnancy experiences: normal birth without complications, high blood pressure during pregnancy, miscarriage, and early or pre-term delivery. This DoD sponsored study is headed by researchers from the Battelle Center for Public Health Research and Evaluation, the University of Texas School of Public Health, and the US Air Force.

This study is designed to discover whether work environments influence pregnancy outcomes. We hope to uncover areas where intervention and improved health care planning for pregnant women can make a difference.

WHAT DOES THIS INVOLVE?

We need to compare the lifestyles, occupational histories, and workplace environments of many different women—both those experiencing problems with their pregnancy, and those with an uncomplicated pregnancy—to detect clues to what may influence these events.

Should you decide to participate, a telephone interview that may last up to one hour will be scheduled to obtain information about your lifestyle and work history. In addition, we will need your permission to access your birth related medical records. We will also review Air Force workplace case files that may exist for jobs you had when you were pregnant.

WHY AIR FORCE WOMEN?

As an Air Force woman, you are part of a unique population because of your occupation and access to excellent health care.

In fact, the Air Force has long supported women in the military, having the highest percentage of women on active duty of any service, the most career fields available to women, and the strongest programs to protect pregnant women and their offspring.

These factors have led us to conclude that studies of Air Force women and their pregnancies will provide answers to medical questions which are available nowhere else.

WHAT HAS BEEN LEARNED SO FAR?

In the first phase of this study we reviewed twenty years of hospitalization records for active duty Air Force women to determine baseline levels of births and adverse pregnancy-related outcomes.

Overall, we found that birth rates were higher among active duty Air Force women than their civilian counterparts. Miscarriages and high blood pressure during pregnancy decreased over time. However, early deliveries have been increasing—reflecting similar patterns in civilian populations.

CONFIDENTIALITY

We will take extreme measures to protect your privacy and confidentiality.

- Your name and social security numbers will not appear in our files.
- Your records will be identified by codes known only to us.
- Your information will be stored in a secure area with access limited only to us.
- Your name will never appear in any reports.
- Results will be presented in such a way that individual participants cannot be identified.
- After 5 years, all information collected for the study will be destroyed.