

**Date of IRB Review: May 2009
81st Medical Group
Keesler AFB, Mississippi**

Exempt (Human) Research Protocol

This is a Progress Report _____ / Final Report XX

1. Protocol Number: FKE20060003E

2. Title: "Perinatal Morbidity and Mortality in the U.S. Department of Defense, 2001-2005"

3. Principal Investigator (PI): Andrew T. Allen, MD, Maj, USAF, MC, FS, 31 MSGS/SGCX, Phone: DSN 314-632-5863, Email: andrew.allen@aviano.af.mil

(Add your rank and full name, squadron/office symbol, telephone number, beeper number)

4. Purpose: *(Copy from your original protocol and paste here)* The risk of death from complications of pregnancy has decreased approximately 99% during the twentieth century, from approximately 850 maternal deaths per 100,000 live births in 1900 to 7.5 in 1982. However, since 1982, no further decrease has occurred in maternal mortality in the United States¹. A recent study by Haas revealed a Maternal Mortality Ratio (MMR) of 5.5 per 100,000 live births within the Department of Defense during the period 1993-1998². This is below the national average, but has not reached the goal of 3.3 per 100,000 set by Healthy People 2010³.

The methods of data collection regarding maternal mortality are variable. The study by Haas cited above utilized Standard Inpatient Data Records (SIDR) from a military database. Other studies, such as performed by Berg, utilize the Center for Disease Control and Prevention's (CDC) Pregnancy-Related Mortality Surveillance System, which accesses data input from the different states' health departments as well as national death files⁴.

Each system of data collection has its own merits and faults depending on the patient population as well as the ultimate use of the information. Extracting accurate information from such a large pool of data can be difficult as well, depending on the accuracy of the information input into each system. This is a well-known weakness of large epidemiological studies, and attempts to minimize such errors are crucial in the development of protocols and data collection instruments.

In 2000 the Department of Defense began using a new system for collecting and storing SIDR data, known as the M2 data repository. Each DOD institution (worldwide) inputs data from the Composite Health Care System (CHCS) into M2 on a regular basis, and information is available for retrieval going as far back as fiscal year 2000. The information collected by M2 is too vast to list in this proposal, but includes many demographic variables, disposition data, as well as diagnosis and procedure codes.

The M2 data repository contains a wealth of information that, when appropriately accessed, can lead to many useful and informative research protocols. We intend to use M2 in this study to determine the rates of maternal and neonatal morbidity and mortality within the U.S. Department of Defense military treatment facilities between 2001 and 2005.

Collecting and reporting this information will be valuable for all Military Treatment Facilities. The rates that will be determined can guide departmental Morbidity and Mortality conferences as well as Quality Assurance meetings in determining how their local facility compares to the rest of the Department of Defense facilities in each category.

5. Status of the Study. Mark the status of the study (a-e).

- a. _____ Active with ongoing data collection. Request approval to remain open.
- b. _____ Active with data collection complete. Request approval to remain open.
- c. _____ Study was never initiated and request termination of the study.
- d. XX Completed, research implemented and results available. Request approval to close.
- e. _____ Inactive, protocol never initiated, but want to keep in open. Request approval to remain open.

Report Documentation Page				Form Approved OMB No. 0704-0188	
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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The risk of death from complications of pregnancy has decreased approximately 99% during the twentieth century, from approximately 850 maternal deaths per 100,000 live births in 1900 to 7.5 in 1982. However, since 1982, no further decrease has occurred in maternal mortality in the United States. The M2 data repository was queried for all vaginal and cesarean births that occurred within all U.S. Department of Defense military treatment facilities from 1 Jan 2001 to 31 Dec 2005 by selecting all encounters that fell under the diagnosis related groups (DRGs) 370-375 (cesarean and vaginal deliveries, with and without complications, and with and without associated procedures). As the overall cesarean rate has increased and the rate of forceps deliveries has decreased, the rates of 3rd and 4th degree lacerations and shoulder dystocia have decreased (58.72 to 41.48 per 1,000 and 29.27 to 22.25 per 1,000 respectively, statistical significance not calculated). The rate of GBS infection has increased from 2001 to 2005 (137.27 to 200.17 per 1,000) which likely reflects the institution of universal screening in 2002, not necessarily an increase in the rate of actual infection.					
15. SUBJECT TERMS Perinatal Morbidity and Mortality; M2;					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT 1	18. NUMBER OF PAGES 5	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

6. Summary of Progress: This report covers the following period of time: August 2006 – May 2009.
Provide a brief summary of any results obtained in the study even if results are not yet statistically significant.

- a. Since last progress report or initiation of study: I am finished collecting data.
- b. For the entire study: I have completed 100% of the study.
- c. If this is a FINAL REPORT:

1. Were the protocol objectives met and how will the outcome benefit the DoD/USAF? The objectives were met, and I review the results periodically to ascertain rates of various delivery modes as well as morbidity. However, since the study was initiated, I became involved with the NPIC (National Perinatal Information Center). The PPIP (Perinatal Performance Information Project) gathers much of the same data that I had gathered, but analyzes it much more in-depth. Therefore, I defer further analysis to the NPIC and request to close the study.
(Answer.....)

2. Protocol Outcomes Summary:

Background: In 2000 the Department of Defense began using a new system for collecting and storing SIDR data, known as the M2 data repository. Each DOD institution (worldwide) inputs data from the Composite Health Care System (CHCS) into M2 on a regular basis, and information is available for retrieval going as far back as fiscal year 2000. The information collected by M2 is too vast to list in this paper, but includes many demographic variables, disposition data, as well as diagnosis and procedure codes. The purpose of this study was to use SIDR data from M2 to determine the rates of maternal morbidity and mortality within the U.S. Department of Defense military treatment facilities between 2001 and 2005.

Methods: The M2 data repository was queried for all vaginal and cesarean births that occurred within all U.S. Department of Defense military treatment facilities from 1 Jan 2001 to 31 Dec 2005 by selecting all encounters that fell under the diagnosis related groups (DRGs) 370-375 (cesarean and vaginal deliveries, with and without complications, and with and without associated procedures). Each encounter included the following variables: maternal age, race, beneficiary category, treatment facility, date of admission, date of delivery, and disposition status; as well as 8 associated International Classification of Disease (ICD-9) diagnosis codes, and 8 ICD-9 procedural codes. No personally identifiable information (such as patient name or social security number) was retrieved during this query. Each encounter's associated ICD-9 diagnosis and procedure codes were tabulated and cross-referenced using Microsoft Access, and Microsoft Excel calculated the rates of the various morbidities.

Results: It is interesting to note that the primary cesarean rate did not increase by much (15.30% to 16.88% from 2001-2005, statistical significance not yet calculated) but the overall cesarean rate has increased from 20.73% in 2001 to 24.30% in 2005, driven by an increase in the repeat cesarean rate (33.33% to 38.28%), decrease in the VBAC rate (28.58% to 16.70%), and decrease in the operative vaginal delivery rate (9.92% to 7.91%). The decrease in operative vaginal deliveries appears to be driven by a decrease in the rate of forceps from 2001 to 2005 (4.33% to 2.27%) as the rate of vacuum deliveries appears to be relative constant (5.41% to 5.54%). Statistical significance has not been calculated. As the overall cesarean rate has increased and the rate of forceps deliveries has decreased, the rates of 3rd and 4th degree lacerations and shoulder dystocia have decreased (58.72 to 41.48 per 1,000 and 29.27 to 22.25 per 1,000 respectively, statistical significance not calculated). The rate of GBS infection has increased from 2001 to 2005 (137.27 to 200.17 per 1,000) which likely reflects the institution of universal screening in 2002, not necessarily an increase in the rate of actual infection.

Rates of delivery

	<i>Total</i>	2001	2002	2003	2004	2005
Total Live Births:	261,020	52,414	53,248	52,950	51,996	50,412
Total Cesareans	59,403	10,864	11,609	12,077	12,605	12,248
Total Prior Cesareans	27,919	5,070	5,680	5,712	5,828	5,629
Primary Cesareans:	37735	7243	7423	7646	7864	7559
Repeat Cesareans:	21668	3621	4186	4431	4741	4689
Total Cesarean rate	22.76%	20.73%	21.80%	22.81%	24.24%	24.30%
Primary Cesarean rate	16.19%	15.30%	15.61%	16.19%	17.03%	16.88%
Repeat Cesarean rate	36.48%	33.33%	36.06%	36.69%	37.61%	38.28%
VBACs:	6251	1449	1494	1281	1087	940
VBAC rate	22.39%	28.58%	26.30%	22.43%	18.65%	16.70%
Total Vaginal	201,617	41,550	41,639	40,873	39,391	38,164
Forcep Deliveries	6326	1801	1456	1200	1002	867
Vacuum Deliveries	11293	2247	2286	2387	2259	2114
Forceps + Vacuum	277	74	43	56	65	39
Operative Deliveries	17896	4122	3785	3643	3326	3020
Forceps rate	3.14%	4.33%	3.50%	2.94%	2.54%	2.27%
Vacuum rate	5.60%	5.41%	5.49%	5.84%	5.73%	5.54%
Operative vaginal rate	8.88%	9.92%	9.09%	8.91%	8.44%	7.91%

Maternal morbidities, with rate per 1,000 live births

	<i>Total</i>	<i>Rate</i>	2001	<i>Rate</i>	2002	<i>Rate</i>	2003	<i>Rate</i>	2004	<i>Rate</i>	2005	<i>Rate</i>
Live Births:	261,020		52,414		53,248		52,950		51,996		50,412	
of cesarean	59,403		10,864		11,609		12,077		12,605		12,248	
of Vaginal	201,617		41,550		41,639		40,873		39,391		38,164	
Failure to progress/ intolerance of labor	92265		18509		18517		18318		18561		18360	
Postpartum hemorrhage/ clotting disorder	33197		6940		7128		6751		6122		6256	
Malpresentation	14338		2983		2863		2902		2921		2669	
Chills/fever/Septicemia	15729	60.26	2964	56.55	3169	59.51	3254	61.45	3226	62.04	3116	61.81
Endometritis/ Salpingitis/ oophoritis	11704	44.84	2173	41.46	2260	42.44	2366	44.68	2486	47.81	2419	47.98
Shoulder dystocia	5297	26.27	1216	29.27	1214	29.16	1111	27.18	907	23.03	849	22.25
Uterine rupture	227	0.87	45	0.86	50	0.94	56	1.06	34	0.65	42	0.83
Amniotic fluid embolism	7	0.03	0	0.00	2	0.04	0	0.00	2	0.04	3	0.06
Pulmonary embolism	40	0.15	6	0.11	6	0.11	15	0.28	5	0.10	8	0.16
Cerebrovascular event	42	0.16	9	0.17	8	0.15	10	0.19	5	0.10	10	0.20
Deep Vein Thrombosis (DVT)	110	0.42	19	0.36	21	0.39	17	0.32	30	0.58	23	0.46
Postpartum hemorrhage	12509	47.92	2644	50.44	2602	48.87	2568	48.50	2420	46.54	2275	45.13
Perineal/3rd/4th degree laceration	9893	49.07	2440	58.72	2191	52.62	1897	46.41	1782	45.24	1583	41.48
Uterine inversion	106	0.53	20	0.48	29	0.70	24	0.59	18	0.46	15	0.39
Vulvovaginal hematoma	815	4.04	132	3.18	204	4.90	197	4.82	166	4.21	116	3.04
Cervical laceration	1115	5.53	223	5.37	194	4.66	219	5.36	324	8.23	155	4.06

Maternal infections per 1,000 live births

	<u>Total</u>	<u>Rate</u>	<u>2001</u>	<u>Rate</u>	<u>2002</u>	<u>Rate</u>	<u>2003</u>	<u>Rate</u>	<u>2004</u>	<u>Rate</u>	<u>2005</u>	<u>Rate</u>
Total Live Births:	261,020		52,414		53,248		52,950		51,996		50,412	
Total cesarean	59,403		10,864		11,609		12,077		12,605		12,248	
Total Vaginal	201,617		41,550		41,639		40,873		39,391		38,164	
GBS	45,088	172.74	7,195	137.27	8,527	160.14	9,574	180.81	9,701	186.57	10,091	200.17
Herpes simplex	3,632	13.91	677	12.92	751	14.10	817	15.43	738	14.19	649	12.87
Syphilis	51	0.20	20	0.38	6	0.11	7	0.13	8	0.15	10	0.20
Tuberculosis	48	0.18	16	0.31	11	0.21	7	0.13	4	0.08	10	0.20
HIV/AIDS	12	0.05	5	0.10	1	0.02	2	0.04	3	0.06	1	0.02

(Please provide in abstract format a summary of the protocol objectives, materials, methods, and results. Include tables/figures, conclusions, and applications)

◀ IF THIS IS A FINAL REPORT PROCEED TO # 9 ▶

7. Protocol Changes:

- a. ☐ No changes are anticipated and the project will continue as previously approved by the IRB.
- b. ☐ Changes are anticipated as described below: (Description... ..)
- c. When do you anticipate PCSing or separating? Indefinite

8. Protocol Personnel Changes: Has there been any Principal or Associate Investigator (PI/AI) changes since approval of protocol or the last continuation review? ☐ Yes ☒ No.

9. Status of Approved Funding: No funding was requested in my original protocol.

10. Publications/Presentations/Awards: N/A

11. Certification of Principal Investigator

My signature certifies that the above titled research has been conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. I understand that a Progress Report is required in order to maintain continuation approval and any changes in the study/methodology must be approved by the IRB prior to implementation. If the study has never been initiated and I am requesting termination (Item 5.c. above), my signature certifies this request. If the study is completed (Items 5.d. & 6.c. above) and I am requesting closure, my signature certifies that the information provided on this form represents an accurate final report.



ANDREW T. ALLEN, Maj, USAF, MC, FS
OB/GYN Staff Physician
31 MSGS/SGCX
Aviano AB, Italy

5 May 2009
Date