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An epidemiologic analysis of SIDS and other deaths as part of the Safe Passage Study in the Northern Plains of the United States and the Western Cape of South Africa

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Abstract

Purpose: To report the infant mortality cause of death and demographic data from sudden infant deaths [SIDS] and known causes of deaths [KCOD] from the live births of a prospective group of pregnant women from the Northern Plains (NP) of the United States and the Western Cape region of the Republic of South Africa (SA).

Methods: Between August 2007 and January 2015, 10,088 women with 11,892 pregnancies were recruited in the Western Cape areas of (SA); and from five sites in the (NP) [North and South Dakota] of the United States, including two American Indian (AI) Reservations.

Results: There were 6,783 SA pregnancies and 4,735 NP pregnancies resulting in 10,727 live births, from which there were 122 infant deaths (88 SA & 34 NP). Forty-five of the 122 deaths were predischarge and 11 (all SA) were listed as unclassified lack of an autopsy or scene investigation prevented classification of a cause of death. The bulk of the analysis was conducted on the remaining 66 infant deaths. The SA/NP Infant Mortality Rates (IMR's) were 13.0/7.1. The SA/NP percentages of SIDS deaths was 26-39%/15%. There were 28 SIDS and 38 Known Cause of Death (KCOD). The SA/NP SIDS rates were 3.39-5.01/1.06. The SA/NP KCOD percentages of deaths were 61%-74%/86% (SA/NP KCOD rates were 7.96-9.58/6.12)[the SA percentage and rate data is given as a range since 11 unclassified cases could have been variably assigned]. Bed-sharing was reported in 68% of the one-month interviews and 88% of the SIDS DSI's.

Conclusions: The SIDS rates and percentages were significantly higher for SA vs. NP and accounted for the significantly higher SA IMR vs. NP IMR. The Study SA IMR is much lower than unofficially reported IMR's in the Western Cape. Bed-sharing was very common and not significantly different between SIDS and KCOD.

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ABBREVIATIONS

SIDS Sudden Infant Death Syndrome; IMR Infant Mortality Rate; KCOD Known Cause of Death; SA South Africa; NP Northern Plains; ND/SD North Dakota and South Dakota; DSI Death Scene Investigation; AI American Indian; CDC Centers of Disease Control and Prevention; SUID Sudden Unexpected Infant Death; IRB Institutional Review Board; WHO World Health Organization

INTRODUCTION

The persistence and quantity of sudden unexpected infant deaths remains a significant health problem worldwide. The causation of these sudden infant deaths, often referred to as the Sudden Infant Death Syndrome (SIDS), has eluded the scientific community; however, several risk factors have been shown to increase the incidence of sudden infant deaths, including (amongst many) asphyxial/unsafe sleeping conditions, prenatal alcohol consumption, prenatal/postnatal tobacco exposure, and genetic defects [1-3].

To study the effects of prenatal alcohol exposure, in August of 2007 through January of 2015 a prospective group of pregnant women was enrolled from residential areas in the Western Cape surrounding Cape Town, South Africa (SA), and five sites in the Northern Plains (NP) of the United States (North and South Dakota – ND/SD) including two American Indian (AI) Reservations (the Safe Passage/PASS study). Since the study's expressed purpose was to evaluate the possible effects of alcohol the study included a protocol for the examination of the inevitable still births and infant deaths amongst the cohort.

Since asphyxial risks are very frequently found in sudden infant death scenes, [4-7] the potential asphyxial risks present in the study's infant deaths were also evaluated. Study asphyxial risks were evaluated using a system developed by Randall. that incorporated asphyxial risk into a classification system.[8] The Randall system was later incorporated, in part, into the Centers for Disease Control and Prevention (CDC) classification system to facilitate registration of infant death cases into a multistate Sudden Unexpected Infant Death (SUID) Case Registry.[9]

Given its prospective design, the Safe Passage Study allowed for the collection of both prepartum and postpartum prospective data for deaths within the study group. This offered a unique opportunity to develop extensive demographic data on a large number of infant deaths – both sudden unexplained infant deaths and known causes of death (KCOD). The inclusion of an assessment of asphyxial risk also allowed for both a comparison with other studies showing an association with asphyxial risks in sudden infant deaths,[7] but also, a comparison of asphyxial risk factors between sudden infant deaths and infant deaths with KCOD's.

MATERIALS AND METHODS

Study design, populations, and settings

The Study sites were selected for high rates of prenatal alcohol use and sudden infant deaths and included populations where marked ethnic and socioeconomic disparities in sudden infant deaths remained understudied. Written informed consent was obtained from each participant at the time of recruitment, which occurred between six weeks gestation up to, but not including, delivery. Depending on gestational age, women meeting eligibility criteria were enrolled and completed (when possible) up to three additional prenatal visits at 20-24, 28-32, and 34+ gestational weeks; maternal-infant dyads were assessed at delivery, one month, and 1-year post delivery. At one-month postnatal age (corrected for prematurity) mothers were interviewed regarding postnatal drinking and smoking behaviors and infant sleep environments; specifically, bed-sharing and sleep position last placed. When a sudden infant demise occurred, complete autopsies (to include genetic testing, microbiologic testing [bacterial and viral] and toxicologic testing) were performed as allowed by local jurisdictional practices. Death scenes were evaluated in situ whenever possible by trained death scene investigators. Otherwise, the death scene information was obtained after the fact by these investigators from the caregivers and first responders at the scene when the death scene could not be immediately viewed. The designation of an asphyxial environment was entirely subjective on the part of the death scene investigator. The participant was asked for written informed consent for release of the autopsy and death scene investigation reports of the infant demise to the study. [10]

Institutional review board (IRB) approvals, including tribal review boards for reservation-based sites in the NP, were obtained for all PASS entities (clinical sites, and centers for data coordination, and pathology and physiology assessment centers). The research was overseen by the network's Steering Committee and an external Advisory and Safety Monitoring Board.

Outcomes

Infants were followed to 1-year post delivery. After reviewing the autopsy reports and death scene investigation reports of each infant death, the causes of infant demises occurring after hospital discharge were adjudicated by a multidisciplinary Pathology Committee consisting primarily of forensic, pediatric, and neuropathologists. Deaths were adjudicated using two classification systems.

In the Study system, sudden infant deaths were defined as SIDS when there was a sudden unexpected death of an infant, less than 1-year of age, whose cause of death remained unexplained after review of all available information, including performance of a complete autopsy, examination or report of the death scene, and review of the clinical history. In reference to the International Classification of Death (ICD) coding schema the Study SIDS cases included deaths that would have been coded as ICD-10 R95 (SIDS) **and** ICD-10 R99 (Unknown). [11] Deaths coded as R99 were included in the Study system because, during the adjudication process, there were multiple cases where there was a lack of consensus regarding whether the infant death was truly unexplained. Unexplained causes (R99) of infant death that were included in the Study definition of SIDS should not be confused with "unclassified" cases (to be discussed below) where an autopsy and/or death scene investigation was not performed.

The second, Randall [8], classification system contained the following categories:

A. SIDS per the Willinger [12], NICHD definition

B. Possibly asphyxial-related

C. Possibly non-asphyxial related

D. Other, to include unknown

E. Unclassified (No autopsy and/or death scene investigation)

F. Known cause of death (KCOD), either of natural or unnatural manner.

Statistical analysis

Statistical analysis was done in SAS 9.4. Rates were calculated out of 1000. Frequencies and rates were compared with chi-square tests, and continuous distributions were compared with t-tests. Significance was determined with $p<0.05$.

RESULTS

During the course of the study there were 10,088 enrolled participants with 11,892 pregnancies (6,783 (SA) and 4,735 (NP). Three hundred and fourteen pregnancies were lost before birth. Six hundred and sixty-nine of the live births were lost to follow-up in the Study.

The data presented below represents an analysis of the 10,849 known live births. All of the SA infants were born to coloured mothers, reflecting the majority of the population in the area. In the NP 2,695 (57%) were born to white mothers and 1,958 (41%) to American Indian (AI) mothers. The above group of pregnancies resulted in 122 live births that subsequently died in the first year of life (88 SA and 34 NP). Although the NP study population was 57% white, approximately half of the NP deaths were AI (AI 18 [51%], white 12 [34%], unknown race 5 [17%]).

Forty-five of the live births died prior to discharge from the birth hospital (18 SA and 27 NP). Of the remaining 77 infant deaths (60 SA and 17 NP), 11 (all SA) of the deaths were listed as unclassified (due to lack of autopsy and/or death scene examination and cases that were excluded due to potential medicolegal concerns regarding the death – comparable to the Randall E category above). Excluding the 11 unclassified cases, 66 infants (49 SA and 17 NP) were the subject of the more thorough review outlined below.

The demographic data of the 66 infant deaths referenced above has been previously published (13) and is shown in (Table 1). Of note from this table: the SIDS (but not the KCOD) rate is significantly higher for SA, lower levels of education were significantly related to both SIDS and KCOD, low pre-pregnancy BMI was significantly related to KCOD (but not SIDS), lower gestational age at delivery was significantly related to both SIDS and KCOD, lower gravidity and parity was significantly related to KCOD (but not SIDS), a previous infant demise was significantly related to KCOD (but not SIDS), low birth weight was significantly related to both SIDS and KCOD, and a male predominance of deaths was not seen.

The total Study-wide infant mortality rate (IMR) was 10.6 (all rates expressed as per 1000 live births). Broken down by region, the total SA IMR was 13.0 versus 7.1 for the NP ($p=.004$). In 2015 the South African national IMR was 28, [14] significantly more than the Study SA rate ($p<0.001$).

The ND/SD IMR (CDC Wonder data [15] was 6.0, less than SA ($p<0.0001$) and NP ($p<0.001$) IMR's, but not statistically more than the US IMR (5.77 $p=0.29$). The national US IMR during the study interval (5.77) was significantly less ($p\leq0.0001$) than the Study IMR or the SA IMR ($p<0.0001$).

The NP Study IMR cannot be directly compared to the ND/SD IMR given the previously cited different racial composition of the NP population versus the ND/SD background population. [15] The ND/SD data however is included as a marker of the background population from which the NP Study data was drawn.

Figure 1 graphically illustrates the percentages of Study causes of death along with comparative graphic representations of percentage causes of infant death in the United States, SA Study (see below), NP Study, and known [16] ND/SD demographic data. For analysis of the US and ND/SD SIDS (Study definition) represents a combination of ICD-10 code R95 (SIDS) and ICD-10 code 99 (Unknown) data.

Since 11 of the SA deaths were unclassified, the percentages of SA SIDS and KCOD reflects a range from none of the unclassified cases (as defined above – no autopsy or scene investigation or an ongoing medicolegal investigation) belonging to a given group (SIDS or KCOD) or all of the unclassified falling into either SIDS or KCOD. None of the 45 predischarge deaths were SIDS. SA data for SIDS and KCOD in (Figure 1) therefore represents the potential ranges for the SA data. Given the above, the SA SIDS percentage ranges from 26% to 39% and KCOD range from 61% to 74%. Data extracted from South African national vital registration information [14] show that SIDS (Study definition) comprised 9% of South African deaths in 2015, significantly less than the SA Study SIDS percentage range ($p<0.0001$).

The NP SIDS percentage (15%) is less than the low SA SIDS percentage (26% $p=0.09$), and comparable to the ND/SD percentage (14%) ($p=0.95$). The NP SIDS percentage (15%) is more than the US percentage (12% $p=0.80$). For KCOD the US (81%), NP (73%), ND/SD (78%) and low to high SA percentages are comparable. [16] The percentage of accidents is higher in the NP (12%) than in the US (7% $p=0.47$) and comparable to the ND/SD (11% $p=0.85$). [15]

The Study, SA SIDS, and KCOD rates given below again reflect

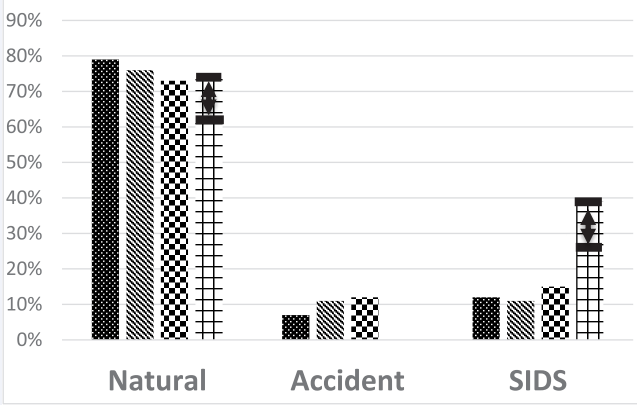

Figure 1 Comparison of Study vs National Infant Deaths.

Table 1: Crude Associations between Infant Outcomes and Enrollment Characteristics.

	Total n=10792[1]	Alive at 1 Year n=10727	SIDS n=28	SIDS Risk/1000[2]	SIDS p-value[3]	Known Cause n=38	Known Cause Risk/1000[2]	Known Cause p-value[3]
Maternal Characteristics								
Recruitment Location					0.009			0.18
Northern Plains	4553 (42.2%)	4536	5	1.10		12	2.64	
South Africa	6240 (57.8%)	6191	23	3.70		26	4.18	
Maternal Age (years)					0.37			0.44
<20	1736 (16.1%)	1729	2	1.16		5	2.88	
20 to <35	8218 (76.2%)	8165	25	3.05		28	3.42	
35+	839 (7.8%)	833	1	1.20		5	5.97	
Race					0.07			0.10
American Indian or Alaska Native	1847 (17.1%)	1835	3	1.63		9	4.88	
Coloured	6222 (57.7%)	6173	23	3.71		26	4.19	
White	2631 (24.4%)	2626	2	0.76		3	1.14	
Other/Unknown	93 (0.9%)	93	0	0.00		0	0.00	
Education					0.01			0.009
Any Primary School	565 (5.2%)	557	3	5.36		5	8.90	
Some High School	4996 (46.3%)	4957	20	4.02		19	3.82	
Completed High School	2205 (20.5%)	2191	3	1.37		11	5.00	
Beyond High School	3018 (28.0%)	3013	2	0.66		3	0.99	
Pre-pregnancy BMI (kg/m)					0.14			0.02
Underweight (<18.5)	569 (7.8%)	561	3	5.32		5	8.83	
Normal (18.5 to <25.0)	3271 (44.9%)	3259	7	2.14		5	1.53	
Overweight (25.0 to <30.0)	1712 (23.5%)	1705	4	2.34		3	1.76	
Obese (30.0 to <35.0)	953 (13.1%)	951	0	0.00		2	2.10	
Morbidly Obese (≥35.0)	775 (10.7%)	771	0	0.00		4	5.16	
Gestational Age at Enrollment					0.83			0.006
First trimester (0 to 97 days)	2611 (24.3%)	2592	8	3.08		11	4.23	
Second trimester (98 to 195 days)	7098 (66.1%)	7063	17	2.40		18	2.54	
Third trimester (≥196 days)	1025 (9.6%)	1013	3	2.95		9	8.81	
Gestational Age at Delivery (weeks)					<0.001			<0.001
<28,0	25 (0.2%)	22	0	0.00		3	120.00	
28 to 31,6	98 (0.9%)	93	4	41.24		1	10.64	
32 to 36,6	1178 (10.9%)	1160	7	6.00		11	9.39	
≥37,0	9486 (87.9%)	9446	17	1.80		23	2.43	

Multi-fetal Pregnancy								0.13				0.58
No		10549 (97.7%)	10486		26		2.47		37		3.52	
Yes		244 (2.3%)	241		2		8.23		1		4.13	
Maternal Obstetric History												
Gravidity								0.14				0.002
1		3391 (31.5%)	3381		3		0.89		7		2.07	
2		3075 (28.6%)	3055		9		2.94		11		3.59	
3		2019 (18.8%)	2005		9		4.47		5		2.49	0.30
4		1183 (11.0%)	1176		4		3.39		3		2.54	
≥5		1098 (10.2%)	1084		3		2.76		11		10.05	
Parity								0.15				0.001
0		3942 (36.6%)	3931		4		1.02		7		1.78	
1		3268 (30.4%)	3247		10		3.07		11		3.38	
2		1932 (18.0%)	1918		8		4.15		6		3.12	
3		963 (9.0%)	955		4		4.17		4		4.17	
≥4		661 (6.1%)	650		2		3.07		9		13.66	
Nulliparous							0.01					0.03
No		6824 (63.4%)	6770		24		3.53		30		4.41	
Yes		3942 (36.6%)	3931		4		1.02		7		1.78	
Previous Stillbirths							0.19					0.06
No		6883 (96.8%)	6835		23		3.35		25		3.64	
Yes		226 (3.2%)	221		2		8.97		3		13.39	
Previous Infant Demise								0.55				0.01
No		6884 (96.8%)	6836		24		3.50		24		3.50	
Yes		225 (3.2%)	220		1		4.52		4		17.86	
Infant Characteristics												
Birth Weight (g)								<0.001				<0.0001
<1500		107 (1.0%)	98		5		48.54		4		39.22	
1500 to <2500		1035 (9.8%)	1015		6		5.88		14		13.61	
2500 to <4000		8631 (81.7%)	8598		16		1.86		17		1.86	
≥4000		796 (7.5%)	794		0		0.00		2		2.51	
SGA (as reported on MCA)								0.06				0.10
No		10376 (98.5)%	10,316		25		2.42		35		3.38	
Yes		156 (1.5%)	152		2		12.99		2		12.99	
Female								0.28				0.49
No		5348 (49.6%)	5316		11		2.06		21		3.93	
Yes		5436 (50.4%)	5402		17		3.14		17		3.4	

a range of possible results given that the unclassified cases may or may not have been SIDS or KCOD. The first given rate reflects the rate had none of the unclassified cases fallen into the group (SIDS or KCOD – equivalent to discarding the unclassified cases from analysis) and the second rate reflecting the rate had all of the unclassified cases fallen into a given group (SIDS or KCOD). Twenty-eight SIDS deaths were recorded in the Study (5 NP and 23 SA).

The total Study SIDS rate was 2.43 – 3.39. Broken down by regions, the SA SIDS rate was 3.39-5.01 and the NP SIDS rate was 1.06. Comparing low-to-low rates, the low SA SIDS rate (3.39) was significantly higher than the NP rate (1.06 p=0.021) and the US SIDS rate [see below] (0.87 p<0.0001). Using 2015 South African national data [14], the South African national SIDS rate for that year was 3.4, comparable to the SA Study SIDS.

Comparing Study SIDS rates to US SIDS rates is hampered by national SIDS definitional problems [1-3, 16] and the large number of unclassified deaths. Official US data [15] (death certificate derived) uses the ICD-10 R95 code for SIDS. The R95 code however does not differentiate between cases strictly adhering to the Study definition and those using a colloquial definition (often meaning any sudden unexplained infant death with or without a DSI). The US SIDS (R95) rate is 0.37 and the US infant death unknown rate (R99) is 0.52. Combining the US R95 & R99 rates equals 0.87, which is comparable to the Study NP SIDS rate (1.06). The background ND/SD white SIDS rate is 0.60 and the AI SIDS rate is 2.04 (which is not significantly higher than the observed NP SIDS rate (1.06 p=0.66). The various KCOD's are enumerated in Table 2. The Accident deaths (4) seen in [Figure 1] all came from NP. Three reflected non-asphyxial physical trauma. There was one death associated with overlaying asphyxia (ASSB ICD-10 code W75). Forty-three of the 45 pre-discharge deaths were natural KCOD. The Study NP accident death rate is 0.8, not significantly different than the US rate 0.4. [14]

For KCOD, the total Study rate was 7.21 – 8.16. By regions, the Study SA KCOD rate (43 KCOD) was 7.96 – 9.58 and for NP (KCOD 39) 6.12. Comparing low-to-low KCOD rates, the SA KCOD rate was not significantly higher than the NP KCOD rates. The US KCOD rate was 5.09, not significantly lower than the NP rate.

In [Table 3], the death classification systems detailed in the Methods Section were applied to the 66 infants delineated above plus the unclassified deaths. By adding the SA unclassified cases (11 - SIDS v KCOD) to the 18 SA Randall B cases suggest that SA percentages with asphyxial potential could vary from 53% (none of the unclassified cases were Randall B's) to 85% (all of the unclassified cases were Randall B's). The number of NP SIDS cases is too small to evaluate further.

Both of the classification systems agreed on the number of KCOD's. Neither of the two classification systems showed a significant difference within systems between NP and SA.

[Table 4] compares the One Month Infant Care Practice data collected from the mothers of all living infants at one month postpartum to the data collected from the DSI for those infants that died. Referencing the SIDS cases, the one-month data shows that only 17 mothers of SIDS infants responded to the Shared Sleep Area Last Night and Sleep Location Last Night queries. Of those 17 respondents, 13 (76%) reported a shared sleeping surface, which was a mattress in 12 (71%) of the cases.

The SIDS DSI data shows that 21 of 24 (88%) of the deaths occurred while bed-sharing. Bed-sharing showed no significant difference between the one-month interview and the DSI (p=0.07). The sleep position was not noted on the one-month interview. Only 2 (8%) of the SIDS infants with a DSI were found supine. The DSI data reported that the majority of the infants were discovered by their mother in the morning.

For the KCOD infant deaths (37 total) there was insufficient DSI information for comparison to the one-month interview. Comparable to the one-month SIDS deaths data, 15 (43%) deaths listed bed-sharing at the one-month interview.

Using the Randall category system, [Table 5] shows SIDS data comparing the One Month Infant Care Practice data (13 respondents in the antemortem data – 4 A's [31%] and 9 B's [69%]) and DSI data (21 cases – 4 A's [19%] and 17 B's [81%]). The SIDS DSI data shows the majority of all deaths

Table 2: Known Causes of Death Diagnoses.

Diagnosis	N
Prematurity Related	21
Respiratory Infection	15
Congenital Malformation(s)	12
Complications of Pregnancy*	11
Accident	4
CNS Infection	3
CNS Miscellaneous	3
Gastrointestinal Infection	3
Cardiac Infection	1
Congenital Rubella	1
Renal Miscellaneous	1
Respiratory Miscellaneous	1
Dehydration	1

Table 3. Infant Death Schema.

	Total	Northern Plains (n=18)	South Africa (n=60)	P-value
	n (%)	n (%)	n (%)	
Randall Schema				0.4559
A: SIDS	6 (8)	1 (6)	5 (8)	
B: Possibly Asphyxial-Related	22 (28)	4 (22)	18 (30)	
C. Possibly Non-Asphyxial Related	0 (0)	0 (0)	0 (0)	
D: Other	1 (1)	0 (0)	1 (2)	
E: Unclassified (No Autopsy and/or Death Scene Investigation)	12 (15)	1 (6)	11 (18)	
F: Known Cause of Death	37 (47)	12 (67)	25 (42)	
Study Schema				0.1362
SIDS	28 (36)	5 (28)	23 (38)	
Unclassified (No Autopsy and/or Death Scene Investigation)	13 (17)	1 (6)	12 (20)	
Known Cause of Death	37 (47)	12 (67)	25 (42)	

Table 4. Comparing 1 month Infant Care Practices to Death Scene Investigation by Study Schema.

Infant Care Practices (Collected at 1 Month)	ALL PASS	SIDS	Known Cause of Death
Total N	9872	28	38
Shared Sleep Area Last Night	6728 (68)	13 (76)	16 (84)
Baby put down in supine position Last Night.	3532 (36)	2 (12)	2 (11)
Sleep Location Found Last Night			
Crib	2503 (25)	2 (12)	3 (16)
Seat	272 (3)	1 (6)	0 (0)
Sofa or Couch	37 (<1)	-	-
Mattress	5736 (58)	12 (71)	11 (58)
Other	1314 (13)	2 (12)	5 (26)
Death Scene Investigation	**SIDS**	**Known Cause of Death**	
Total N	28	38	
Someone Sleeping with Infant	21 (88)	4 (80)	
Position Deceased Found			
Sitting	1 (4)	-	
On back	2 (8)	1 (20)	
On side	15 (60)	2 (40)	
On stomach	6 (24)	1 (20)	
Unknown	1 (4)	1 (20)	
Sleep Location Found			
Crib	3 (12)	3 (60)	
Seat	1 (4)	-	
Sofa or Couch	-	-	
Mattress	13 (52)	1 (20)	
Other	8 (32)	1 (20)	
Witness Relationship to Deceased			
Birth Mother	24 (92)	3 (60)	
Birth Father	1 (4)	1 (20)	
Other	1 (4)	1 (20)	
Witness is Usual Caregiver	22 (88)	3 (75)	
Time Deceased Discovered			
Middle of Night/Early Morning (12-5AM)	7 (28)	2 (40)	
Morning (5-10AM)	15 (60)	3 (60)	
Afternoon	3 (12)	-	

Table 5. Comparing 1 month Infant Care Practices to Death Scene Investigation by Randall Schema.

Infant Care Practices (Collected at 1 Month)	ALL PASS	A: SIDS	B: Unclassified (Asphyxial-Related)	F: Known Cause of Death
Total N	9872	6	21	38
Shared Sleep Area Last Night	6728 (68)	4 (80)	9 (82)	16 (84)
Baby put down in supine position Last Night.	3532 (36)	1 (20)	1 (9)	2 (11)
Sleep Location Found Last Night				
Crib	2503 (25)	1 (20)	1 (9)	3 (16)
Seat	272 (3)	-	-	0 (0)
Sofa or Couch	37 (<1)	-	-	-
Mattress	5736 (58)	4 (80)	8 (73)	11 (58)
Other	1314 (13)	-	2 (18)	5 (26)
Death Scene Investigation	**A: SIDS**	**B: Unclassified (Asphyxial-Related)**	**F: Known Cause of Death**	
Total N	6	21	38	
Someone Sleeping with Infant	4 (80)	16 (89)	4 (80)	
Position Deceased Found				
Sitting	1 (17)	-	-	
On back	-	2 (11)	1 (20)	
On side	3 (50)	11 (61)	2 (40)	
On stomach	2 (33)	4 (22)	1 (20)	
Unknown	-	1 (6)	1 (20)	
Sleep Location Found				
Crib	-	3 (17)	3 (60)	
Seat	1 (17)	-	-	
Sofa or Couch	-	-	-	
Mattress	3 (50)	10 (56)	1 (20)	
Other	2 (33)	5 (28)	1 (20)	
Witness Relationship to Deceased				
Birth Mother	6 (100)	17 (89)	3 (60)	
Birth Father	-	1 (5)	1 (20)	
Other	-	1 (5)	1 (20)	
Witness is Usual Caregiver	6 (100)	15 (83)	3 (75)	
Time Deceased Discovered				
Middle of Night/Early Morning (12-5 AM)	2 (33)	5 (28)	2 (40)	
Morning (5-10 AM)	3 (50)	11 (61)	3 (60)	
Afternoon	1 (17)	2 (11)	-	

were discovered in the morning (83%). The positions found for Randall Groups A and B were comparable as was the comparison between Groups A and B for bed-sharing.

Figure 2 illustrates the Study age distribution for SIDS and KCOD (the figure does not include unclassified cases). The difference between the SIDS age distribution versus KCOD is not significant (p=0.22). Of the 111 deaths represented in this figure, 45 KCOD died pre-discharge from the hospital (primarily prematurity related deaths), skewing this analysis. The remaining 66 (28 SIDS [42%] and 38 KCOD [58%]) died post-discharge.

DISCUSSION

The Safe Passage Study was conceived as a large prospective study of pregnancy outcomes to determine whether alcohol and tobacco smoking contributed to an increase in SIDS. That alcohol and smoking were significantly associated with SIDS was conclusively shown by the work of Elliott [13].

The Study, with its prenatal and postnatal data collection and death scene investigations, also offered the opportunity to explore the epidemiology of the resultant deaths that occurred within a cohort of live births. It was apparent from the beginning

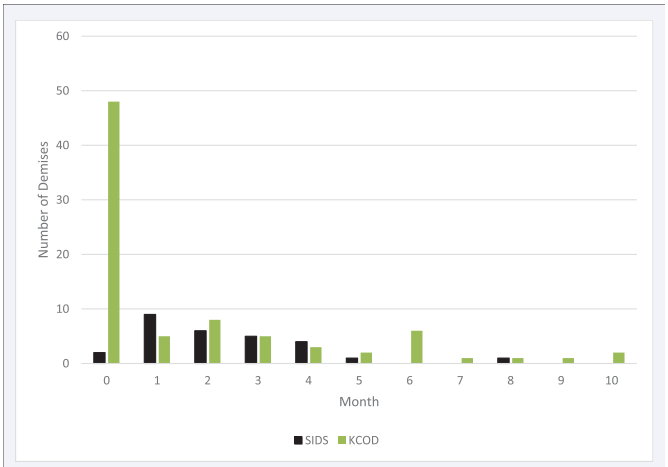

Figure 2 Infant Demises by Month Postpartum.

that the infant deaths resulting from the Study would not be comparable to a large-scale epidemiologic review of infant deaths such as those derived from death certificate data or data from large death investigation agencies. Rather, the Safe Passage Study data would offer more of a "snap-shot" sampling of the infant deaths occurring in a particular communities in the Western Cape of South Africa (SA) and the Northern Plains (NP) of the United States.

The Study resulted in a total of 11,518 live births and 122 deaths. Forty-five of the 122 deaths died prior to hospital discharge and were not studied further other than to be included in the KCOD data and the infant mortality rates discussed below. The 45 pre-discharge deaths were all Known Causes of Death (KCOD). The remaining 77 infant deaths were more rigorously studied regarding causes and circumstances of death.

The term Sudden Unexpected Infant Death (SUID) has become popular as a vehicle to categorize sudden infant deaths. It has been published that SUID can be viewed as the combination of SIDS (ICD coded as R95), Unknown (ICD coded as R99) and Accidental Suffocation or Strangulation while in Bed (ASSB, ICD coded as W75). [16] A consensus was reached that the Study would classify any infant death as SIDS when the cause of death was unknown after a thorough investigation (representing a combination of deaths that would have been coded as R95 + R99).

The Study had an overall Infant Mortality Rate (IMR expressed as number of deaths per 1,000 live births) of 10.6. Broken down by Study sites, the SA rate was 13.0, significantly less than the comparable South African national IMR (2015) of 28. [15] The NP rate was 7.1, significantly higher than the comparable US IMR of 5.77, as would be expected from the known higher ND/SD AI IMR (10.8) [14].

For the time period covered by the study, the United Nations [17] quoted IMR's for South Africa, ranging from 45 in 2007 to 28.5 in 2015, while a Demographic and Health Survey for 2016 quoted a national IMR of 35 [18]. Another publication showed an IMR of 19.3 for the Western Cape in 2013 and a very similar IMR for Cape Town. [19] All of these figures are much higher than the SA IMR of 13.1.

The reason for the large disparity between South African reported IMR's and the Study IMR is unclear. One possible explanation may reflect the possibility that some mothers in the SA cohort chose to opt out of the autopsy part of this study, preventing those demises from being captured in the data. Excluding these cases from analysis would thereby lower the SA IMR. Given the historical apparent lack of robust vital data reporting in South Africa (see below), the South Africa IMR's given above may be overestimated.

Additionally, from the outset of the Study there was concern that the prenatal and postnatal visits that were part of the Study would result in fewer infant deaths than would be expected in the background population (the Hawthorne effect [20, 21]). That could further explain the lower Study IMR. Unfortunately, we did not have a separate cohort that did not receive any pre-natal or post-natal follow-up whose data could answer the question of a Hawthorne effect in this Study. Furthermore, the number of deaths recorded in the study is less than that envisioned in the initial Study proposal, which may suggest that infant mortality was declining between the onset and conclusion of the Study.

The calculation of SIDS and KCOD rates and percentages for the Study was significantly challenged by the large number of unclassified deaths (cases lacking a DSI or autopsy - all in SA). Any given unclassified death could potentially (had the appropriate criteria been met for the case to have been included) been classified as either SIDS or KCOD. Therefore, the Study SIDS and KCOD rates have to be expressed as a range where the low number represents none of the unclassified cases included in the SIDS or KCOD rates while the high-rate number represents the situation had all of the unclassified deaths been included in a given category (SIDS or KCOD).

The Study SIDS rates were 2.43 – 3.39. The SA SIDS rates were 3.95 – 5.01. The lower SA SIDS rate (3.95) was significantly higher than the US rate (0.89 p=0.001) and the NP SIDS rate (1.06).

Unfortunately, complete official South African infant death data are unavailable for the years of the Study. Molteno et. al. published a Cape Town SIDS rate of 3.05. [22] However, the Molteno data has serious deficiencies: it reflects 1984 data, the method for establishing an infant's cause of death was unclear, and autopsy examinations were not routine. Studies of Cape Town infant deaths [23-25] in fact make no mention of SIDS or sudden infant deaths, although one [25] does categorize 15% of deaths as "ill-defined" and 16% of deaths as "other."

Why the South Africa and Study SIDS rates are so high is unclear. It could, of course, simply reflect a lack of public health awareness, and prevention strategies, for reducing risk factors for SIDS. As discussed below, the common occurrence of bed-sharing in the SA Study cohort may bear that out to some extent. As pointed out in the above paragraph, another possible explanation is that infant deaths in South Africa are being misclassified. It is possible that the SA Study death scene investigators, and South African infant death investigation in general, may be biased towards calling deaths SIDS that other investigators may have classified as asphyxial (particularly since calling a death asphyxial is largely subjective on the part of the investigator). This is potentially supported by the low number of

accident deaths in both South Africa and the absence of accident deaths in the SA Study data.

It also is unclear why the Study SA SIDS percentage is so much higher than the reported South African, NP, and US SIDS percentages. Given the presumed lower socioeconomic conditions in South Africa versus the United States, one could have expected KCOD's to be higher in South Africa/SA. This may well be true for South Africa nationally. In the Study however, KCOD percentages and rates appear to be comparable to NP and US data. As alluded to above, the Hawthorne effect may have not only have decreased the Study IMR, but may have preferentially reduced the number of Study KCOD's (which would have the effect of increasing the percentage of SA Study SIDS).

Given the higher percentage and rates of SIDS in SA (without even adding potential SIDS cases from the unclassified category), and the absence of a significant KCOD differences in either percentages or rates between SA and NP, it appears that SIDS, rather than KCOD, is primarily responsible for the SA IMR being higher than the NP, ND/SD, or US IMR data. If SIDS reflects the primary difference between SA, ND/SD, and total US infant mortality, then this may suggest that large differences do not exist between medical infant health care for KCOD in the NP versus Study SA.

The demographic data in [Table 1] confirmed some of the known risk factors associated with SIDS to include low birth weight and low maternal education. [1-3] Surprisingly, factors often associated with increased SIDS rates, such as low pregnancy BMI, a previous infant demise, or male sex, were not significantly related to an increased rate of SIDS. We have no explanation why the Study population did not mimic the same risk and demographic factors associated with SIDS that have been seen in many other previous studies.

The information in [Table 1] may, however, inform healthcare approaches in these populations. Factors that were significantly associated with KCOD may reflect poor maternal health and/or health education. For example, low pre-pregnancy BMI, low birth weight and lower levels of education. Moreover, KCOD occurred more commonly where mothers had lower gravidity and parity, suggesting that a lack of parenting experience may have caused them not to recognize serious medical concerns in their infants. In populations that are geographically or socio-economically isolated, interventions to guide young mothers regarding sign of disease in their babies may go far to prevent unnecessary deaths.

Figure 2 shows the age distribution of the Study deaths. The Study mirrors numerous other studies that SIDS predominately occurs in the first six months of life. [1-3] The KCOD spike in the first month reflects prematurity and congenital abnormality deaths in the 45 predischarge deaths.

It is unclear why the Study recorded such a small number of accident deaths in SA. The Cape Town infant death studies referenced above (22-26), for example, listed up to 12% of the deaths as accident. [Figure 1] illustrates a comparable percentage of accidental infant deaths in the US and the NP region while no accident deaths were reported in SA. The absence of traumatic accidental deaths in SA, despite being shown in published infant death studies, [14] suggests that there were accidental SA deaths not captured by the Study. This lack of capture may reflect that only 94.2% of the live births were followed to one year, potentially reflecting, in part, a bias against including accident deaths in the Study. It is also possible that some accident deaths were lumped into the unclassified category.

In the US, the Accidental Strangulation or Suffocation in Bed (ICD-10 ASSB code W75) accounts for 24% of sudden infant deaths. [15] ASSB is an extremely subjective diagnosis, and it is quite possible that the adjudication and/or scene investigation process was biased against using it versus SIDS in this study. ASSB was not documented as a KCOD in SA and only once in the NP. South African national raw data show that only one case was coded as W75 in South Africa in 2015 – perhaps suggesting a national bias against the use of the W75 code. Limited information is available in previous South African studies regarding accidental deaths in the infant population, but interestingly, one South African study listed 4% of deaths due to suffocation in children 5 years of age or younger. [25]

Several studies have shown that unsafe sleeping environments with asphyxial potential are present in a large percentage of sudden unexpected infant deaths.[4-7] Since the Randall classification system has shown efficacy in uncovering asphyxial related infant deaths in the United States [8], it was included in the Study to capture those infants dying in potentially asphyxiating situations. Disregarding the unclassified cases, approximately 79% of the SIDS cases died in a potentially asphyxiating environment (applying the unclassified cases the asphyxial percentages vary from 56% to 85%), which is comparable to the percentages seen in other studies cited above. During the adjudication process it was quite common in the DSI (particularly in the SA cohort) to see entire families sleeping together on the same sleeping surface (usually a mattress). Almost all of these households lacked a crib.

However, the incidence of potentially asphyxiating environments was comparable between the SIDS and KCOD groups. The Randall system therefore offered no insight between differentiating between SIDS and KCOD. The Randall system however did reveal that 17% of the SIDS cases did not have an asphyxial risk (consistent with other potential non-asphyxial correlations with SIDS such as temperature, genetic defects, and infection) [1-3, 28]

Table 4 documents a high incidence of reported unsafe sleeping amongst the Study deaths. The unsafe sleeping environments (a designation limited since it is anecdotally and subjectively derived) however were equivalent between the SIDS and KCOD deaths at the one-month interviews, suggesting that unsafe sleeping was nearly ubiquitous in the Study and not confined to SIDS. Of particular note was the high incidence of sleeping on a mattress and non-supine sleeping.

A previous study [27] has shown that the medullary serotonin defects originally described in SIDS cases [28] were equally present in a US population of Randall A and B cases. The PASS Study may suggest that when an external stressor becomes nearly ubiquitous, the "triple-risk model" [29] may become a "double-risk model", or other external stressors less frequently associated with SIDS are active in the Study (e.g. acute upper

respiratory viral infections, parental drug/alcohol/tobacco use, extremes of temperature, etc.).

In the United States, sleeping on a couch/sofa is a well-known unsafe sleeping practice associated with many sudden infant deaths. [4-7] In Tables 4 and 5 there were no Study infant deaths associated with couch/sofa sleeping. In fact, less that 1% of the mothers interviewed at the one-month postpartum visit reported couch/sofa sleeping.

Although we did not keep definitive records, the DSI scene photos in many cases showed the lack of a couch/sofa in the home, which may explain the lack of couch/sofa related deaths in the Study.

A 2005 comparative analysis by the World Health Organization (WHO) rated South African death registration data as poor quality, in part due to a high proportion of deaths recorded with ill-defined causes of death. [30] Similarly, Burger [31] found in 2007 that 43% of death notification forms in their Cape Town based study had major errors, and 15% of all cases in their study had ill-defined causes of death.[32] These problems have been ascribed to poor training in death certification [33] and hesitancy amongst doctors to report "sensitive" causes of death (such as HIV infection).[31,32,33] For the reasons enumerated above, caution must be exercised in comparisons of SA Study data with regional of national South African data. We are particularly concerned that the South African national SIDS numbers [14] may be inaccurate.

The authors acknowledge that a major deficit in the Study is the small number of deaths occurring during the Study (particularly in the NP) and the large number of unclassified cases. It is regrettable that further information was not available/collected on the surviving infants beyond the one-month interview. However, given the small number of deaths in relation to the large number of infants involved in the one-month interview a substantial majority of the one-month data represents survivor data. It was indeed a failure of the Study design that more thorough investigation of post-neonatal survivors was not done. Specifically, it would have been of great interest to know how many of the presumed bed-sharing survivors seen at the one-month interview ultimately survived. Hopefully this issue can be addressed in a subsequent publication.

We recognize that conclusions regarding the circumstances surrounding these deaths must be cautiously interpreted. However, this manuscript is a unique report of the outcomes of 11,892 pregnancies in two geographically diverse locations with known high prevalence of alcohol abuse. [13] The fact that the overall numbers of deaths are low may in and of itself be instructive. The overall distribution of deaths is informative, particularly in regions without other official mortality data.

CONCLUSION

The prenatal and postnatal follow-up of the Study participants appears likely to have reduced the incidence of infant SA deaths compared to what might have been predicted. For example, in the absence of readily available government statistics, the SA (Western Cape) IMR (13.0) is considerably less than reported IMR's of 23 - 25 in that region. A similar reduction however was not seen in the NP.

The Study IMR and SIDS rates were significantly higher for the community in the Western Cape of South Africa than for the Northern Plains of the United States. Despite the Study protocol's potential reduction in the number of infant deaths, the SA SIDS rate (3.4 – 5.1) is the only recent estimation of a Western Cape SIDS rate and appears to be greater than what has been previously published (3.05), but is comparable to the South African national SIDS rate, 3.4, in 2015. The SA SIDS rates and percentages appear to represent the major difference between the SA and NP infant deaths. The Study NP SIDS rate and percentage was not significantly different than the background population rate and percentage, but were higher than the US rate.

Rates and percentages of KCOD were not significantly different between SA, NP, ND/SD, and the US. Unsafe sleeping practices (as reported in previous literature) were extremely common in the Study deaths. As a result, the Randall Classification System was not able to efficiently separate those deaths with, and without, unsafe sleeping environments. Accidental deaths were likely under reported in the Study, particularly in SA.

Risk factors commonly associated with SIDS (low pregnancy BMI, and a previous infant demise) were, for unknown reasons, not associated with SIDS in the Study.

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