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Trends and recurrence of stillbirths in NSW

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Abstract

Objective: To examine the trend in stillbirth rates adjusted for the trends in the maternal risk profile, and to use local data to estimate the stillbirth recurrence risk.

Methods: Linked hospital, birth and perinatal death review data were used to identify risk factors and stillbirths among women giving birth to singletons in NSW between 2001 and 2009. Logistic regression models were developed to predict stillbirth rates based on the changes in the maternal population.

Results: Between 2001 and 2009 there were 3449 stillbirths (4.4 per 1000 births), with no significant change in rate overall (p=0.6) or across older gestational age categories (26-33 weeks p=0.67, >=34 weeks p=0.36), and a slight increase at <26 weeks (p=0.01). However, when changes in the maternal population were taken into account, there was a significant increase in stillbirths at <26 weeks (p<0.001). Women with a stillbirth in a first pregnancy were at increased risk of stillbirth in their second pregnancy (4.3 95% CI (2.4,7.7)).

Conclusion: There has been no decline in the stillbirth rate in NSW in recent years, which at late gestations may be accounted for by changes in the maternal population. At early gestations, there has been an increase in stillbirths where a decrease in rate may be expected based on the maternal population.

Implications: Further focus on addressing risk factors for stillbirths is needed to ensure continued progress is made in reducing stillbirths.

Introduction

The death of a baby, either before or after its birth is a devastating thing for a family, and can have long term consequences for those involved. In NSW, the perinatal death rate (stillbirths and deaths within 28 days of birth) is around 9 per 1000 of which 70% of these are stillbirths.[1] Advances in treatment of preterm infants, and an associated increase in preterm deliveries have seen a decline in the overall perinatal death rate in many countries,[2] however the decline in the rate of neonatal deaths has been faster than in stillbirths.[3, 4] Since the nineties, there has been little progress made towards reduction of the stillbirth rate across many higher income countries, including Australia,[3, 5, 6] New Zealand,[7] United States,[8] Italy[9] and the United Kingdom.[10] It is significant that over the same period the nature of the maternity population has been changing, with increasing numbers of women having risk factors for stillbirth including advanced age, comorbid conditions, and use of artificial reproductive technologies.[11, 12] However, at the same time, other risk factors, including maternal smoking[13] and teenage mothers,[14] have been decreasing. The unadjusted stillbirth rates typically reported do not take such changes in risk factors into account. This raises the possibility that alterations in risk factor profile of the maternal population disguise progress made in the prevention of stillbirths.[15, 16]

We used reported risk factors for stillbirth to compare the predicted and actual stillbirth rates in NSW between 2001 and 2009, to determine if changing maternal characteristics accounted for the apparent lack of progress in preventing stillbirth. We also used linked data to determine the recurrence risk for stillbirth.

Methods

The study population included all singleton births in NSW between 2001 and 2009, but was limited to births of gestational age ≥22 weeks or birthweight ≥500g after investigation showed that there had been an increase in reporting of stillbirths of 20-21 weeks/400-499g birthweight since 2005, coinciding with a change in reporting requirements.[17] Pregnancy terminations did not change over time and were excluded.

Data were obtained from up to three linked population data sources. Pregnancy, labour, delivery and outcome related data were obtained from the Perinatal Data Collection (PDC), a statutory surveillance system containing information on all births in NSW. The Admitted Patients Data Collection (APDC), which collects procedures and diagnoses associated with every hospitalization in NSW, coded according

to the 10th revision of the International Classification of Diseases, Australian Modification (ICD10-AM) and Australian Classification of Health Interventions (ACHI). Additional data on fact of death for stillbirths were obtained from the NSW Perinatal Death Review (PDR) database. These data are collected from confidential reviews carried out by the NSW Maternal and Perinatal Committee, which reviews stillbirths and neonatal deaths of at least 22 weeks gestation or 500 grams birth weight (or at least 20 weeks gestation or 400 grams birth weight if born after 2005).[17] Probabilistic linkage was undertaken by the Centre for Health Record Linkage (CHeReL), and de-identified data were provided to the researchers with a linkage key enabling linkage of all records belonging to a mother and her infant. All three datasets were used to identify possible stillbirths using an algorithm, described elsewhere, for the best identification of stillbirths in population health datasets.[18]

Potential risk factors highlighted in the literature were identified from maternal admissions during pregnancy and childbirth. These were sourced from the APDC or PDC (or both) depending on the reliability of reporting in each source based on validation studies.[19, 20]

Due to differences in potential risk factors at early and late gestations, stillbirths were classified as occurring before 26 weeks gestation, between 26 and 33 weeks or at 34 weeks or later. These strata were selected on the basis of differing risk factors and pathophysiology.[4, 21, 22] Within each stillbirth group, the overall trend in stillbirth rates, and trends in risk factors were assessed using the Cochran Armitage test for trend, and univariate odds ratios and 95% confidence intervals were calculated to determine the strength of the relationship between each risk factor and stillbirth. Three-year moving averages were calculated to minimize observed fluctuations due to the small number of stillbirths each year.

To determine whether observed stillbirth rates were higher or lower than would be expected given any changes in risk factors in the maternity population, we compared the observed stillbirth trend with predicted trends that account for population changes. If the predicted rates are close to the observed rates, it would suggest that the lack of change in stillbirth rates is explained by maternal risk factors.[23] Differences between the observed and predicted stillbirth probabilities were assessed using two-sided binomial tests. Using all births in 2001-2002, predictive models for stillbirth were developed for each of the three gestational age strata. Risk factors showing a significant relationship with stillbirth within this sample were progressively entered into each model until all risk factors significant at $p<0.1$ were included. Additional risk factors were included to maximize the predictive ability of the model (c

statistic). For example, although there was no change in the proportion of fetuses with congenital anomalies or in the association with stillbirth, inclusion of anomalies in the models improved the model fit. The comparison group for stillbirths prior to 26 weeks was all births, for 26 to 33 weeks was all births at or after 26 weeks, and for stillbirths at or after 34 weeks, was all births after 34 weeks. This approach is referred to as 'fetuses at risk' analysis, and is best practice for presenting gestational age specific stillbirth rates, as it reflects the cumulative risk of stillbirth.[24, 25] Data from subsequent years were applied to the 3 regression equations to account for the actual changes in maternal factors over time and produce the predicted trends for 2001-2009. Births which had missing data on one or more risk factor were excluded from this analysis.

The stillbirth recurrence rate was calculated for women with a first and second singleton birth recorded. All analysis was undertaken in SAS 9.3 (SAS Institute, USA). Ethical approval was obtained from the NSW Population and Health Services Research Ethics Committee.

Results

Between 2001 and 2009 there were 780,685 singleton births in NSW, including 3449 stillbirths, giving a stillbirth rate of 4.4 per 1000 births. There was no significant change in the overall stillbirth rate between 2001 and 2009 (p=0.6, Figure 1). Stillbirths at <26 showed a slight increase (p=0.01), but no other gestational age subgroup showed a significant trend (26-33 weeks p=0.67, >=34 weeks p=0.36). Of the 2061 births under 26 weeks gestation, there were 905 stillbirths (1.6 per 1000 fetuses at risk). For the 10752 births between 26 and 33 weeks, there were 1000 stillbirths (1.3 per 1000 fetuses at risk). For births at or after 34 weeks, there were 767,801 births including 1519 stillbirths (rate 2.0 per 1000 fetuses at risk). Complete risk factor information was available for 773,089 births (99.0%).

Table 1 presents the unadjusted and adjusted odds ratios for stillbirths by gestational age group. It also flags the risks that changed over the study period.

Among risk factors for stillbirth *before 26 weeks*, the proportion of older mothers, Aboriginal women, those from lower socioeconomic backgrounds, women using artificial reproductive technology, with antepartum haemorrhage/abruption, and those with a previous preterm birth, or previous stillbirth increased (Table 1). The predictive model had good predictive ability (c statistic=0.79). The predicted

rate decreased from 1.5 in 2001 to 0.99 in 2009, while the actual rate increased from 1.1 in 2001 to 1.3 in 2009 (Figure 2a). The actual stillbirth rate in 2009 was 34% higher than predicted (p<0.001).

Amongst risk factors for stillbirth *between 26 and 33 weeks*, the proportion of Aboriginal women, women from lower socioeconomic background, women with previous stillbirth or preterm births increased, along with rates of obesity, preexisting diabetes, use of artificial reproductive technologies, and antepartum haemorrhage (Table 1). The predictive model for risk of stillbirth prior to 34 weeks had good predictive ability (c=0.75), and the predicted stillbirth rate decreased from 1.3 per 1000 births in 2001 to 1.1 per 1000 in 2009. In comparison, the actual stillbirth rate decreased from 1.3 per 1000 in 2001 to 1.1 in 2009, suggesting the decrease in stillbirth rate was in line with what would be expected with the change in maternal risk factors. (Figure 2b)

Amongst risk factors for stillbirth *at or greater than 34 weeks* gestation, maternal age, and the proportion of Aboriginal, low SES, and obese women were increasing, as were the proportion of women with pre-existing diabetes, antepartum haemorrhage or placental abruption, and those experiencing problems during labour. Other risk factors, including pregnancy hypertension and infection have decreased since 2001 (Table 1). The predictive model for risk of stillbirth at or after 34 weeks gestation had reasonable predictive ability (c=0.69), and the predicted stillbirth rate remained constant at 2.0 between 2001 and 2009, whereas the actual stillbirth rate decreased from 2.0 in 2001 to 1.9 per 1000 in 2009 (Figure 2c). The actual stillbirth rate in 2009 was 6% lower than predicted given the change in maternal population over that time, however this was not statistically significant.

Of the 145,437 women with information on their first and second sequential births, the rate of stillbirth was 6.0 per 1000 births for a first pregnancy, and 3.3 for a second pregnancy. For women with a stillbirth in their first pregnancy, the recurrence rate was 13 per 1000 (OR=4.3 95% CI (2.4,7.7)). 2)). In a second pregnancy the odds of recurrence for early stillbirth (<26 weeks) (OR 14.6 (95%CI(3.5,59.8)) and for stillbirth at or after 26 weeks was 4.7 (95% CI 2.3,9.4).

Discussion

We report no change in the stillbirth rate in NSW between 2001 and 2009. Over the same time period there have been changes in stillbirth risk factors. Births to women of higher risk groups increased including older mothers, lower socioeconomic status, obese, diabetic, women with previous stillbirths or preterm births, and infants conceived using ART, commonly reported risk factors for stillbirth.[10, 26-28] Conversely, there were contemporaneous decreases in other high risk groups including teenage mothers, smokers, infection, pregnancy hypertension and some chronic conditions, which are also known risk factors for stillbirth.[15, 28, 29 30] Accounting for such changes in maternal factors over time, the stillbirth rate was predicted to decrease across all three gestational groups considered. However amongst infants under 26 weeks gestation the stillbirth rate was significantly higher than expected, suggesting that changes in maternal characteristics cannot fully account for the lack of change in stillbirth rate at early gestation. We also found that a woman having a stillbirth in her first pregnancy was at increased risk of stillbirth in her second pregnancy.

The stillbirth rate in births before 26 weeks gestation was around 30 percent higher than expected based on the changes in the maternal population, and had increased 20 percent since 2001. This may be due to increased ascertainment and reporting of stillbirths at the edge of viability, however a lack of decline in stillbirths at early gestations has been reported elsewhere. In the United States, there was no change in the stillbirth rate for births prior to 28 weeks between 1990 and 2003, whereas the stillbirth rate from 28 weeks declined.[8] The largest declines in stillbirth rates in the US between 1995 and 2005 were seen in late preterm and term births.[31] In Canada, increases have been seen in stillbirths both prior to 22 weeks (not considered in our study) and between 22 and 27 weeks gestation, however the increase was seen among terminations of pregnancy,[32] which were excluded from both the US study and ours. This Canadian study also assessed the impact of the changing maternal population on trends in spontaneous stillbirth (excluding terminations), and found that the downwards trend observed was not considerably altered following adjustment for maternal factors.

The risk factors for stillbirth in our population were similar to those reported elsewhere. In a meta-analysis of potentially modifiable risk factors for stillbirth in high income countries, Flenady et al found that maternal overweight and obesity, advanced maternal age, primiparity, placental abruption and pre-existing hypertension and diabetes to be the main potentially modifiable risk factors.[28] Of these, only chronic hypertension was not identified in our adjusted models, although it was significant in univariate

models. Other risk factors identified in our study included small birthweight for gestation,[10] low socioeconomic status,[10, 28] previous stillbirth or preterm birth,[26, 27] Aboriginality[15, 33] and maternal country of birth[34] which have been reported elsewhere.

Differences in the relative importance of causes of stillbirths over different gestational ages have been noted elsewhere.[4, 10, 35] The Stillbirth Collaborative Research Network found the majority of stillbirths before 24 weeks gestation to be due to obstetric complications (such as placental abruption and preterm labour) and infections, compared with after 24 weeks where placental disorders were associated with a higher proportion of stillbirths.[4] We found risk factors differed across gestational age, reflecting different aetiology with fetal anomalies and infection associated with stillbirth at early gestation; anomalies, and APH across 26-33 weeks; vasa praevia, infection, and diabetes impacting on late stillbirths, and growth restriction being a strong predictor across all gestations. Growth restriction as a predictor of stillbirth was also reported by Gardosi, who found fetal growth restriction to be the strongest predictor of stillbirth across all gestations.[10]

While many of the observed risk factors for stillbirth are potentially unavoidable, it has been suggested that a high proportion of stillbirths are attributable to factors amenable to change,[28] and that the large variation between stillbirth rates between high income countries gives scope for the reduction of stillbirth rates.[15] The New Zealand Perinatal and Maternal Mortality Review Committee estimated that as many 15% of stillbirths in that country were potentially avoidable.[7] Public health initiatives focusing on pre-pregnancy weight loss and reduction of smoking amongst women of reproductive age have been suggested as potential areas of focus in order to reduce stillbirths.[10, 36-38]

Other risk factors which are increasing, such as older mothers, Aboriginal or overseas born women, history of preterm or stillbirth, diabetes, and APH, although termed 'modifiable' in some studies,[28] are not easily amenable to public health interventions. Early identification of these risk factors during antenatal visits, and careful management of these women through the course of their pregnancy offer the best strategy for reducing stillbirth associated with these factors.[15, 28, 33] Our study found lower risk of late stillbirth in women who had commenced antenatal care prior to 20 weeks gestation. Reduction in stillbirth through early identification and appropriate management of growth restricted fetuses has been identified as a potential benefit of regular antenatal care.[10, 39]

The increased risk of stillbirth in a second pregnancy following a stillbirth in a first pregnancy is consistent with findings of other studies.[27, 40] The range of reported recurrence rates (8-37 per 1000) is consistent with the 13 per 1000 reported here. [41, 42] Women with a previous stillbirth may need additional support in subsequent pregnancies, although there is little evidence to guide the clinician in management of these women.[43] Interestingly, having had a previous stillbirth conferred the highest risk of a subsequent stillbirth at <26 weeks or 26-33 weeks compared to ≥34 weeks (Table 1). When restricted to consecutive births, the overall odds of stillbirth in a second pregnancy was 4.1 for women with a previous stillbirth compared with women without a previous stillbirth, however for recurrent stillbirths at <26 weeks the OR was 13.6. A Norwegian study similarly demonstrated higher risks of early preterm stillbirth recurrence than term stillbirth recurrence.[40] Although based on small numbers, for women who have had an early stillbirth in a first pregnancy, are have progressed past 26 weeks uneventfully in their second pregnancy, this result is potentially reassuring.

This study used linked hospital and birth data for all births in NSW to determine the trends and risk factors for stillbirths. The size of the dataset enabled the identification of relevant risk factors, and to examine potential trends. Use of both hospital and birth data allowed for consideration of a range of medical conditions not routinely collected in the birth data alone. Longitudinal linkage of subsequent births to each woman allowed for consideration of pregnancy history, and for calculation of the stillbirth recurrence risk. Stillbirth reporting has been shown to be reliable over time,[44, 45] and identification of stillbirths from several datasets increased ascertainment. A limitation of administrative datasets for research purposes is the lack of clinical detail on causes for stillbirths, and data on some known risk factors were not available in the administrative data set. Obesity, and drug and alcohol use were collected from hospital data, but this would only be recorded if the risk factor contributed to a hospitalization at some stage during the pregnancy, and so represent the most severe cases. Other major risk factors are well reported in our data sources.[19, 45] This study examined trends in stillbirth over a limited time period, and while additional years of data would have been beneficial, the shorter time period allowed for maximising the available data, and thus improving the reliability of the models.

Conclusion:

Overall, stillbirth rates in NSW have failed to decrease in recent years. There is evidence at later gestations that in part this is due to the changing nature of the obstetric population. Indeed, stillbirth rates at or after 34 weeks are close to what would be expected given the risk profile of the obstetric

population. However, the stillbirth rate at early gestation (under 26 weeks) has increased in a context where changes in maternal risk factors predict a decreasing rate. To reduce the stillbirth rate, interventions should be targeting maternal smoking and obesity, and the early identification and improved management of medical conditions such as hypertension and diabetes.

Table 1: Risk factors for stillbirths, 2001-2009

	Overall		<26 weeks		26-33		34+	
Risk factor	**Live births**	**Still births**						
	N (%)	N (%)	OR (95% CI)	aOR (95% CI)	OR (95% CI)	aOR (95% CI)	OR (95% CI)	aOR (95% CI)
Maternal age <20**	29966 (3.94)	183 (5.4)	1.5 (1.2,2.0)		1.7 (1.3,2.2)	1.1 (0.62,1.9)	1.2 (0.9,1.5)	0.7 (0.42,1.2)
Maternal age 35+*	160807 (21.14)	798 (23.53)	1.2 (1.0,1.4)	1.4 (0.98,2.1)	1.1 (1.0,1.3)	1.5 (1.03,2.1)	1.2 (1.0,1.3)	1.6 (1.19,2)
Australia/NZ born**	567365 (74.6)	2459 (72.52)	1 (0.8,1.1)	1.3 (0.91,1.9)	1 (0.8,1.1)		0.9 (0.8,1.0)	
ATSI*	24434 (3.21)	204 (6.02)	2.1 (1.6,2.7)	6.7 (2.96,15.3)	2.3 (1.8,2.9)	1.6 (0.93,2.8)	1.7 (1.3,2.1)	1.3 (0.8,2.2)
Low SES*	111232 (14.62)	652 (19.23)	1.4 (1.7,1.6)		1.4 (1.2,1.6)		1.5 (1.3,1.7)	1.1 (0.8,1.6)
Married*	635834 (83.6)	2588 (76.32)	0.7 (0.6,0.9)		0.6 (0.6,0.7)		0.7 (0.6,0.7)	
Private	257607 (33.87)	777 (22.91)	0.6 (0.6,0.8)	0.7 (0.49,1)	0.6 (0.5,0.7)	0.6 (0.45,0.9)	0.6 (0.5,0.7)	0.7 (0.5,0.9)
Regional**	219480 (28.86)	1020 (30.08)	0.9 (0.8,1.1)		1.1 (1.0,1.3)		1.2 (1.0,1.3)	
Smoker**	119727 (15.74)	815 (24.03)	1.5 (1.3,1.8)		1.8 (1.5,2.0)		1.8 (1.6,2.0)	1.3 (0.97,1.6)
Alcohol	822 (0.11)	18 (0.53)	3.1 (1.0,9.5)		7.7 (3.8,15.4)		4.5 (2.1,9.5)	
Drug**	7116 (0.94)	78 (2.3)	2.9 (1.9,4.4)		2.6 (1.7,3.9)		2.4 (1.7,3.4)	
Obese*	2000 (0.26)	19 (0.56)	0.8 (0.2,3.4)		2.7 (1.3,5.8)		2.6 (1.4,4.9)	2.7 (0.64,11.3)
Preexisting diabetes*	3294 (0.43)	56 (1.65)	1 (0.4,2.7)		4.1 (2.5,6.6)	3.2 (0.94,10.6)	5.8 (4.1,8.1)	4.8 (2.07,11.0)
Chronic hypertension	6043 (0.79)	73 (2.15)	3 (1.9,4.6)		3.3 (2.2,4.9)		2.4 (1.6,3.5)	
COPD**	10524 (1.38)	40 (1.18)	0.6 (0.3,1.3)		1.3 (0.8,2.05)		0.7 (0.5,1.2)	
Renal condition	2404 (0.32)	19 (0.56)	2.5 (1.2,5.2)		1 (0.3,3.0)		2 (1.0,3.9)	2.6 (0.81,8.1)
Thyroid condition**	3109 (0.41)	18 (0.53)	0.3 (0.0,1.9)		2.5 (1.4,4.7)	2.8 (0.89,9.0)	1.2 (0.6,2.5)	
Psychiatric condition**	5953 (0.78)	36 (1.06)	1.1 (0.6,2.3)		1.7 (1.0,3.0)		1.3 (0.8,2.2)	
Cardiac condition**	3976 (0.52)	38 (1.12)	2.1 (1.2,4.0)		2.2 (1.2,3.9)		2.3 (1.4,3.7)	
Haemoglobinopathy**	1287 (0.17)	9 (0.27)			2.4 (0.9,6.5)		2 (0.8,4.8)	
Cholestasis*	3420 (0.45)	15 (0.44)	0.2 (0.0,1.8)		0.9 (0.3,2.4)		1.5 (0.8,2.9)	

Epilepsy**	1510 (0.2)	8 (0.24)	0.6 (0.1,4.0)		1 (0.3,4.1)		1.7 (0.7,4.2)	
Primiparous	320696 (42.16)	1569 (46.27)	1.2 (1.1,1.4)	1.1 (0.8,1.6)	1.2 (1.0,1.3)	1.3 (0.98,1.8)	1.2 (1.1,1.4)	1.3 (1.02,1.7)
Previous stillbirth*	5977 (0.79)	57 (1.68)	3.3 (2.2,5.0)	4.4 (2.1,9.3)	2.9 (1.9,4.5)	1.9 (0.6,6)	1.1 (0.6,1.9)	
Previous preterm birth*	34509 (4.54)	260 (7.67)	2.5 (2.0,3.1)		2.1 (1.7,2.6)		1.2 (0.9,1.5)	1.5 (0.96,2.4)
Previous caesarean*	103436 (13.6)	444 (13.09)	1 (0.8,1.2)		1.1 (0.9,1.3)		0.9 (0.8,1.0)	
Antenatal visit before 20 weeks*	691523 (90.92)	2957 (87.2)	1.2 (0.9,1.5)		0.7 (0.6,0.9)		0.7 (0.6,0.8)	0.8 (0.58,1)
Artificial reproductive technology use*	9598 (1.26)	48 (1.42)	2.2 (1.4,3.2)	1.9 (0.5,7.7)	0.9 (0.5,1.6)		0.7 (0.4,1.2)	
Cervical incompetence	1972 (0.26)	45 (1.33)	18 (13.1,24.8)		0.8 (0.2,3.3)		0.9 (0.3,2.8)	
Infection**	7275 (0.96)	246 (7.25)	15.5 (12.8,18.8)	10.4 (6.7,16.2)	5.4 (4.0,7.2)	3.2 (1.64,6.4)	7.1 (5.6,8.8)	4 (2.42,6.7)
Pregnancy hypertension**	57756 (7.59)	318 (9.38)	0.9 (0.7,1.1)	0.4 (0.2,0.9)	1.6 (1.3,1.9)	1.6 (1.09,2.4)	1.4 (1.2,1.6)	1 (0.66,1.4)
Antepartum haemorrhage/abruption*	19726 (2.59)	456 (13.45)	7.5 (6.3,9.0)	7.5 (5.0,11.1)	6.6 (5.5,7.9)	6.1 (4.02,9.1)	5.1 (4.3,6.0)	4.2 (2.87,6.1)
Vasa Praevia	342 (0.04)	7 (0.21)					11.1 (5.3,23.6)	11 (2.57,46.8)
Placenta praevia*	4710 (0.62)	16 (0.47)			1.7 (0.89,3.11)		0.7 (0.3,1.6)	
Labour problems*	262645 (34.53)	1075 (31.7)	0.7 (0.6,0.8)	0.5 (0.4,0.8)	0.6 (0.48,0.65)	0.3 (0.22,0.5)	1.3 (1.2,1.5)	1.2 (0.96,1.5)
Fetal anomalies	2250 (0.3)	278 (8.2)	41.2 (33.5,50.8)	15.4 (8.7,27.2)	38.9 (31.56,47.94)	18.6 (11.19,30.9)	18.6 (14.6,23.6)	7.5 (4.07,13.8)
Less than 3rd centile birthweight**	23983 (3.15)	670 (19.76)	7.9 (6.7,9.3)	7.1 (4.9,10.3)	8.8 (7.52,10.18)	11.2 (8.27,15.2)	6.7 (5.9,7.6)	5.4 (4.06,7.2)

* Significant increase over time

** Significant decrease over time

Comparison group is women not having that risk factor

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