Detection of small for gestational age babies and perinatal outcomes following implementation of the growth assessment protocol (GAP) at a New Zealand tertiary facility: an observational study.

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### Abstract

Objective: To assess the impact of implementation of GAP in a multi-ethnic population with high obesity and high deprivation. Design/Methods: Retrospective before (2012) and after (2017) study (pre-and post-GAP). Outcomes were compared between epochs with adjustment for New Zealand Deprivation Index, maternal body mass index, ethnicity, cigarette smoking and age. Setting: Counties Manukau tertiary maternity facility, Auckland, New Zealand Population: Singleton, non-anomalous pregnancies, booked with a hospital midwife by 20 weeks' gestation, with birth after 24 weeks' gestation. Main Outcome Measures: Antenatal detection of SGA babies (<10th customised centile), labour induction, caesarean section and composite adverse neonatal outcome (neonatal unit admission >48 hrs, 5-minute Apgar Score <7, any ventilation). Results: Antenatal detection of SGA increased after introduction of GAP from 22.9% to 57.9% (aOR=4.81, 95% CI 2.82, 8.18) with similar SGA rates across epochs (13.8% vs 12.9%; p=0.68). Induction of labour and caesarean birth increased between epochs, but this increase was similar in SGA and non-SGA. Amongst SGA, increased antenatal identification post-GAP appeared to be associated with lower composite adverse neonatal outcome (identified SGA: pre-GAP 32.4% vs post-GAP 17.5%, aOR=0.44, 95% CI 0.17, 1.15; non-identified SGA: pre-GAP 12.3% vs post-GAP 19.3%, aOR=1.81, 95% CI 0.73, 4.48; interaction p=0.03). Conclusions: GAP was associated with an almost 5-fold increased likelihood for SGA detection, without significant increase in maternal intervention and some evidence of a reduction in composite adverse neonatal outcome in identified SGA pregnancies. GAP is a safe, effective tool for SGA detection in an ethnically diverse population with high obesity levels.

## Introduction

Small for gestational age (SGA) babies are over represented amongst stillborn infants with a population attributable risk between 23% and 31%. <sup>1</sup> Antenatal identification of SGA infants, along with optimal management of SGA, has been associated with reduced severe perinatal morbidity and mortality. <sup>2,3</sup> Therefore, timely identification of the SGA fetus is a critical component of antenatal care, <sup>4</sup> and yet less than 25% of SGA fetuses are usually detected before birth with routine antenatal care.<sup>5</sup>

The Growth Assessment Protocol (GAP) is a multifaceted educational programme that incorporates: standardised training in fundal height measurement; SGA risk selection; specialist review and a schedule of growth scans for high risk pregnancies; serial fundal height measurement and plotting fundal height on a

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customised growth chart; a protocol for ultrasound scanning in low risk pregnancies according to fundal height measurements; and an evidence-based guideline for management if SGA is detected. Implementation of GAP in UK centres has been associated with increased detection of SGA and a parallel reduction in stillbirth.<sup>6</sup> There are few publications reporting implementation of GAP outside of the UK <sup>7</sup> and few data about how implementation of GAP impacts on maternal and perinatal morbidity. GAP is being implemented in several New Zealand District Health Boards but its effectiveness in the New Zealand setting is currently unknown.

This study aimed to assess the effect of implementation of GAP on detection of SGA babies and maternal and neonatal outcomes at Counties Manukau Health (CM Health), a tertiary obstetric facility in South Auckland, New Zealand. CM Health is the largest provider of maternity services in New Zealand, serving an ethnically diverse population, with high rates of obesity and high socio-economic deprivation as well as the highest perinatal mortality in New Zealand. <sup>8</sup> We hypothesised that implementation of GAP would result in improved antenatal detection of pregnancies with SGA babies and that amongst SGA pregnancies, there would be an increase in induction of labour, no increase in caesarean section and a reduction in composite adverse neonatal outcome.

# Methods

#### **Core Outcomes**

The primary outcome was the proportion of SGA pregnancies that were detected before birth and secondary outcomes included: induction of labour, caesarean section, pre-term and post-term birth and composite adverse neonatal outcome defined as one or more of: neonatal unit admission for >48 hours, Apgar score <7 at 5 minutes or infant requiring any ventilation.

No funding was obtained to carry out the study and there was no patient involvement in the planning of this project.

#### Study population:

Pre-GAP epoch: The Pre-GAP cohort comprised all mothers who gave birth between January 1st and December 31st, 2012 in CM Health maternity facilities who received care by hospital employed staff. This was prior to widespread use of GROW charts and before introduction of the New Zealand Maternal Fetal Medicine SGA guideline in 2013. <sup>9</sup> Births under the care of self-employed midwives were excluded as clinical records were not accessible. Further exclusions comprised booking >20 weeks and 0 days, no maternal height or weight recorded, multiple pregnancy, baby born <24 weeks and 0 days or with a major congenital anomaly (Figure 1).

The data were obtained through the following CM Health databases; (1) Healthware <sup>TM</sup>, which is used for recording and storing clinical data; (2) the patient information management system (PiMS<sup>TM</sup>), primarily used for tracking, coding and resource allocation; (3) Concerto, a clinical workstation which allows access to clinical records including ultrasound scan reports, and (4) the Costpro system (for information on clinical coding). Data included: maternal age, ethnicity, New Zealand Deprivation Index, <sup>10</sup>parity, date of last menstrual period (LMP), estimated date of delivery (EDD) by LMP, EDD by ultrasound scan, gestation and weight at booking, height, smoking, pre-existing hypertension, pre-eclampsia, stillbirth, induction of labour, mode of birth, date of delivery, gestation at birth, sex of baby, birth weight, Apgar score at 5 minutes, any neonatal ventilation, admission to the neonatal unit for >48 hours, and neonatal death. Missing data were obtained from clinical notes and data-points that were major outliers were checked by searching the clinical notes.

The New Zealand bulk birthweight centile calculator version 6.7.8, 11 was applied to all births with SGA

defined as birthweight  $<10^{\rm th}$  customised centile. The notes of all women whose babies were SGA at birth were hand checked to ascertain whether SGA was detected by ultrasound scan. Antenatal detection of SGA was defined as an ultrasound estimated fetal weight (EFW) below the tenth customised centile, abdominal circumference  $<5^{\rm th}$  centile, or sequential measurements of estimated fetal weight or abdominal circumference with slow or no growth, and/or one or more abnormal Doppler findings. In cases where detection of SGA was uncertain after review by FJC further review was undertaken by LMEMcC.

**Post-GAP epoch**: The post-GAP cohort comprised all mothers who gave birth between April 1<sup>st</sup> 2017 and March 31<sup>st</sup> 2018, in CM Health maternity facilities and who received care by hospital employed staff. The GAP programme was introduced in February 2016. Exclusions were as per the pre-GAP cohort (Figure 1).

The process of data collection differed from the pre-GAP cohort as by 2017 all maternity records were electronic, after the introduction of the maternity clinical information system (MCIS) in 2015. All post-GAP data was retrieved from the MCIS, PiMS<sup>TM</sup>, Concerto and Costpro systems, with similar data checking and calculation of customised birthweight centiles as for the pre-GAP cohort. An independent audit of detected SGA/FGR was conducted by two final year medical students who were trained by the lead investigator and reviewed all SGA pregnancies to determine whether SGA was detected in the antenatal period or not. In cases where detection of SGA was uncertain after review by the medical students, further review was undertaken by FJC, using the same criteria as for the pre-GAP epoch.

#### Implementation of GAP

The implementation of GAP at CM Health commenced in February 2016 with a series of workshops. Clinicians were provided with an SGA risk assessment tool and management algorithm, summarising the major risk factors for SGA, appropriate care plan depending on risk of SGA, and a guide to management once SGA is suspected (Supplementary Figure 1). Education is scenario based and interactive, with a focus on training in standardised fundal height measurement, accurate use and interpretation of GROW charts, and evidence-based management of SGA pregnancies, according to the New Zealand Maternal Fetal Medicine SGA guideline. A written test is completed by attendees to assess learning at completion of the workshop. Additionally, an e-learning programme is available for consolidation, and it is recommended that clinicians undertake this annually.

# **Analyses**

Analyses were conducted using SAS 9.4 (SAS Institute INC., Cary, NC, USA). Maternal characteristics were compared between epochs using chi-square and t-test, for categorical and continuous data, respectively. Primary and secondary outcomes were compared between epochs by logistic regression, with exposure (epoch) effect expressed as odds ratio and 95% confidence interval (CI). Analyses were adjusted for potential confounding by factors known to be associated with SGA, including the New Zealand Deprivation Index, ethnicity, maternal age, BMI, and cigarette smoking. Two-tailed alpha level was set at 0.05.

Subgroup analysis was undertaken to determine if SGA status influenced exposure (epoch) effect. Further subgroup analysis was undertaken among cases of SGA to determine if antenatal detection of SGA influenced exposure (epoch) effect. Secondary analyses explored if the exposure (epoch) effect on primary outcomes differed by maternal subgroups (SGA vs non-SGA and detected SGA versus undetected SGA).

### Results

The pre-GAP and post-GAP cohorts included 1105 and 1082 women, respectively (Table 1). Between epochs there were significant changes in the characteristics of the study populations with fewer young and older

mothers, and more Asian and fewer Pacific women in the Post-GAP epoch. There was also a change in BMI distribution with more women with a BMI of  $18.5-24.9 \text{ kg/m}^2$  and  $25 \text{ to } 29.9 \text{ kg/m}^2$  in the post-GAP epoch. Fewer women smoked in pregnancy in the post-GAP epoch. There was a small reduction in gestation at delivery and birthweight between epochs, but no change in SGA rates (pre-GAP 13.8% [153/1105] vs post-GAP 12.9% [140/1082]; p=0.53).

Antenatal detection of SGA increased significantly from 22.9% (33/153) pre-GAP to 57.9% (81/140) after introduction of GAP (aOR=4.8, 95% CI 2.82, 8.18; p<0.0001). Detection of SGA was more pronounced for Maaori and Pacific Island women (18.9% pre-GAP vs 63.8% post-GAP, aOR=7.76, 95% CI 3.72, 16.19) compared to women of other ethnicities (28.6% vs 52.1%, aOR=2.60, 95% CI 1.25, 5.39) (interaction p=0.049) (Table 2). Detection of SGA was similar amongst smokers and non-smokers, women living in high and low deprivation, women with and without preeclampsia and by BMI categories.

Induction of labour and caesarean birth increased between epochs, but increases were similar among SGA and non-SGA pregnancies and did not differ by SGA identification status (Table 3). Preterm birth also increased between epochs in both non-SGA and SGA but there was no significant increase in preterm birth in detected SGA pregnancies and no significant interaction between detected and undetected-SGA. In contrast, there was a reduction in overall post-term birth between epochs.

There was a significant increase in overall composite adverse neonatal outcome between

epochs (Table 3). This increase was statistically significant in non-SGA babies (5.3% pre-GAP vs 9.8% post-GAP; aOR=1.98, 95% CI 1.38, 2.84) but not amongst SGA babies (16.9% pre-GAP vs 18.2% post-GAP; aOR=1.05, 95% CI 0.55, 1.10), although the evidence for a difference in epoch effect between SGA versus non-SGA subgroups was not strong (interaction p=0.09).

In the SGA sub-group, there was some evidence that increased identification of SGA post-GAP may be associated with lower composite adverse neonatal outcome (SGA identified: 32.4% pre-GAP vs 17.5% post-GAP; aOR=0.44, 95% CI 0.17, 1.15; SGA non-identified: 12.3% pre-GAP to 19.3% post-GAP; aOR=1.81, 95% CI 0.73, 4.48); (interaction p=0.03).

## Discussion

# **Main Findings**

Our primary hypothesis, that GAP would increase detection of SGA, was confirmed. A novel feature was that we could explore the efficacy of GAP on detection of SGA by maternal demographic and clinical characteristics. While GAP was associated with increased detection of SGA amongst all ethnic groups, it was encouraging to note the more pronounced effect amongst women from Maaori and Pacific Island ethnic backgrounds. Additionally, it was reassuring to note similar SGA detection in women who smoked compared with non-smokers, and in women with the highest deprivation compared with other deprivation groups. As obesity is an independent risk factor for both SGA and stillbirth, 12 it was also encouraging to note the high SGA detection rate (66.7%) amongst women with a BMI >35 kg/m<sup>2</sup>.

While we hypothesised that GAP would be associated with an increase in induction of labour amongst women with SGA pregnancies our data did not demonstrate this effect. A possible explanation could be that the stratified induction approach recommended by NZ GAP education (9) includes induction of labour by 38 weeks for SGA pregnancies with evidence of fetal growth restriction (EFW<3<sup>rd</sup> centile or Doppler velocimetry abnormalities), and expectant management with induction by 40-41 weeks for SGA pregnancies without evidence of fetal growth restriction. A similar stratified approach implemented in Oxford, United Kingdom, has also been associated with a reduction in induction of labour.

Our hypothesis that there would be no increase in caesarean birth amongst SGA pregnancies after implementation of GAP was also not confirmed. Overall, caesarean birth rates rose post-GAP at CM Health, but there were similar increases in SGA and non-SGA subgroups, and the magnitude of the effect did not differ between SGA and non-SGA pregnancies. Importantly, caesarean birth did not increase in the subgroup of SGA pregnancies identified before birth.

There was a significant increase in composite adverse neonatal outcome between epochs in non-SGA but not amongst SGA babies. Further in the SGA subgroup, there was evidence that increased identification of SGA post-GAP may be associated with lower composite adverse neonatal outcome and reduced prolonged neonatal unit admission. While we cannot determine the factors contributing to the better neonatal outcome amongst identified SGA we speculate that improved antenatal detection of SGA has resulted in closer monitoring and timely birth that has contributed to these findings.

#### Strengths and Limitations

This is the first New Zealand study to evaluate implementation of GAP. The New Zealand maternity service is unique in that most women have continuity of midwifery care. Our study focussed entirely on data from hospital employed midwives as data on detection of SGA were not available for self-employed midwives in CM Health. While this may be considered a limitation, hospital employed community midwives at CM Health work in a continuity of care model for antenatal care, and as such, our findings likely represent the New Zealand continuity of care model of working in partnership with a named midwife for each woman. <sup>15</sup> Furthermore, our evaluation was carried out in a multi-ethnic, high deprivation community with high rates of co-morbidities, such as obesity.

A strength of this study is that datasets for pre- and post-GAP were almost 100% complete after extensive checking of handwritten and electronic records. Multivariable analysis adjusted for confounding variables which are known risk factors for SGA and an interaction model was applied to assess the impact of epoch on outcomes.

A limitation is that this study was retrospective with reliance on data from hospital records. Antenatal detection of SGA in the pre-GAP epoch was determined after review of the clinical records and ultrasound reports by the lead investigator who was also the GAP educator. However, in cases of uncertainty, a final decision was made by the senior investigator. This could have introduced ascertainment bias favouring non-detection of SGA in the pre-GAP epoch. Similarly, in the post-GAP epoch, a final decision on uncertain cases was made by the lead investigator. Over the four-year period, between the pre- and post-GAP audits, there were significant demographic and clinical practice changes, and it is possible that increasing awareness of the use of GROW charts and the New Zealand Maternal Fetal Medicine Network (NZMFMN) SGA guideline (first published in 2013) may have resulted in an incremental increase in SGA detection over the intervening years between epochs.

Our study was underpowered to investigate the impact of GAP on stillbirth and neonatal death and had limited power to investigate changes in composite adverse neonatal outcome. We also did not have data on utilisation of ultrasound scans in the respective study populations or data on false positive identification of SGA during either epoch.

## Interpretation

Our results compare well with the most recently published observational study on antenatal detection of SGA following implementation of GAP in an Australian hospital clinic setting. <sup>7</sup> Antenatal SGA detection rates increased significantly following implementation of GAP from 21% to 41% (OR=2.6, 95% CI 1.3, 4.9). Consistent with our findings, these authors also reported reduced overall neonatal unit admission after implementation of GAP. Pre-GAP, admission of SGA babies to the special care nursery was 18% compared to 12% post GAP whereas admission of SGA babies to the neonatal intensive care unit was 5% pre-GAP

and 4.8% post-GAP. The effect of antenatal identification of SGA on other measures of neonatal outcome was not reported.

#### Conclusion

In our study, which is the first to evaluate the effect of implementation of GAP in a New Zealand District Health Board where women receive continuity of midwifery antenatal care, we found that introduction of GAP was associated with an almost five-fold increased likelihood of detection of SGA. While there was an increase in maternal intervention and preterm birth between epochs, this effect was not more pronounced in SGA pregnancies.

Amongst SGA babies who were identified during pregnancy, there was some evidence of reduced composite neonatal morbidity and reduced prolonged neonatal admission. GAP is a safe tool for increasing detection of SGA and suitable for application in an ethnically diverse population with high levels of obesity. Future studies should be powered to detect perinatal mortality and severe morbidity, and also to detect the impact of GAP on false positive diagnosis of SGA and on utilisation of ultrasound scanning.

# Acknowledgements:

#### Disclosure of Interests

FJC is an educator for the New Zealand GAP programme. LMEMcC was the lead author on the NZMFMN SGA Guideline. No conflicts of interest were declared by other authors. Completed disclosure of interest forms are available to view online as supporting information.

## Contribution to Authorship

All authors met authorship criteria. FJC, LMEMcC, JMcA-C and NG contributed to the concept and design of the study. AO'B and FJC performed searches, screening and data extraction. FJC, LMEMcC, JW and CMcK analysed the data. FJC and LMEMcC drafted the manuscript. RST formatted the tables and diagrams, and assisted in editing the manuscript. LMEMcC, JMcC-C, and NG supervised the study and contributed to interpretation of data. All authors reviewed draft versions of the manuscript and accepted the final version. LMEMcC is the senior author on this manuscript.

# Transparency declaration

As the lead author, FJC affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted.

### Details of ethics approval

Ethical approval was obtained through the Auckland University of Technology Ethics Committee (approval number 16/68) on 6<sup>th</sup> December 2016.

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