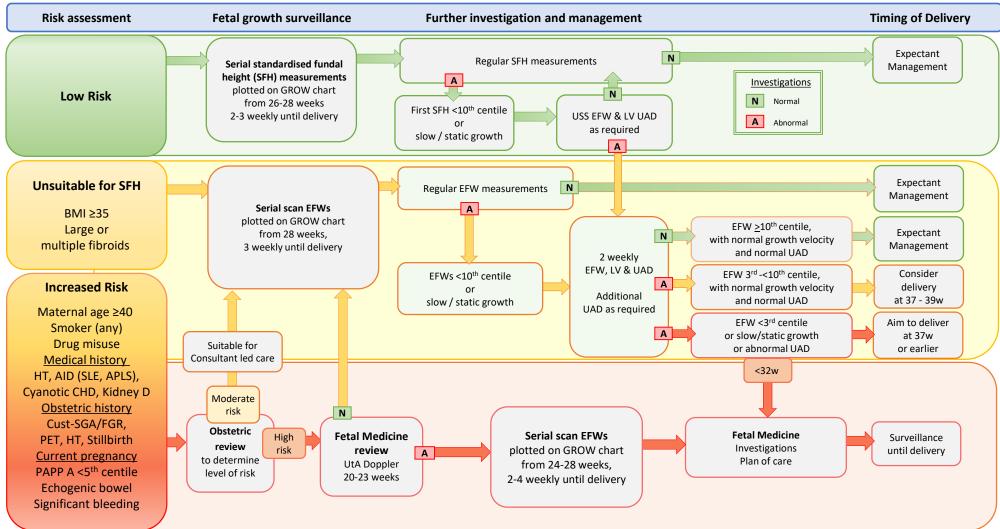
GAP Care Pathway (Phase I)

Risk assessment, surveillance, investigation and management



TO BE USED IN CONJUNCTION WITH EXPLANATORY NOTES



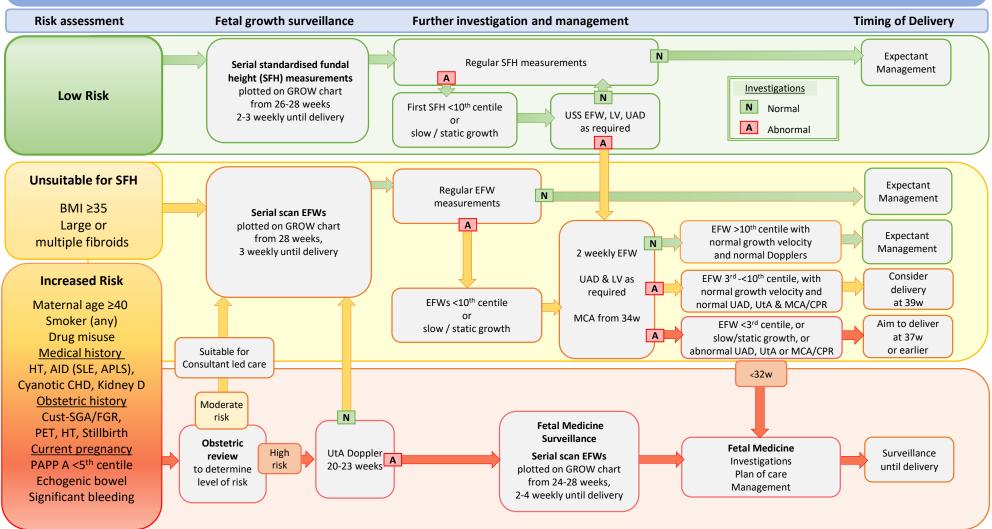
Abbreviations: AID= Autoimmune Disease; APLS= Antiphospholipid Syndrome; BMI= Body Mass Index; CHD= Coronary Heart Disease; CPR= Cerebro-Placental Ratio; EFW= Estimated Fetal Weight; FGR= Fetal Growth Restriction; SFH= Standardised Fundal Height; HT= Hypertension; LV= Liquor Volume; MCA = Middle Cerebral Artery; PET= Pre-eclampsia; SGA= small for gestational age; SLE= systemic lupus erythematosus; UAD= Umbilical Artery Dopplers: UtA = Uterine Artery Doppler. See 'GAP Care Pathway v2 - Explanatory Notes'

GAP Care Pathway (Phase II)

Risk assessment, surveillance, investigation and management



TO BE USED IN CONJUNCTION WITH EXPLANATORY NOTES



Abbreviations: AID= Autoimmune Disease; APLS= Antiphospholipid Syndrome; BMI= Body Mass Index; CHD= Coronary Heart Disease; CPR= Cerebro-Placental Ratio; EFW= Estimated Fetal Weight; FGR= Fetal Growth Restriction; SFH= Standardised Fundal Height; HT= Hypertension; LV= Liquor Volume; MCA = Middle Cerebral Artery; PET= Pre-eclampsia; SGA= small for gestational age; SLE= systemic lupus erythematosus; UAD= Umbilical Artery Dopplers: UtA = Uterine Artery Doppler. See 'GAP Care Pathway v2 - Explanatory Notes'

GAP Care Pathway v2 - Explanatory Notes

27 November 2019



Introduction

Following publication of NHS England's Saving Babies' Lives Care Bundle version 2 (CBv2) earlier this year [1], the Perinatal Institute has begun consultations on how to align and adapt it for NHS Trusts in the GAP programme, while maintaining the benefits of a tried and tested protocol that has been credited as a main factor in the recent reduction of stillbirth rates in England [2, 3, 4].

Our new care pathway seeks to balance the need to identify, investigate and appropriately manage atrisk pregnancies with the aim to avoid unnecessary intervention. It continues the emphasis on surveillance according to risk assessment, by standardised fundal height (SFH) measurement in low risk pregnancy and serial estimated fetal weight (EFW), both plotted on customised charts to improve the distinction between constitutional and pathological smallness [5, 6, 7, 8, 9]. A focus of the revised pathway is a new, evidence based definition of slow growth (see Section B).

Concerns about the ultrasound and Doppler capacity demands of CBv2, expressed at the National GAP User Symposium in July 2019 have led us to conduct, in association with the British Medical Ultrasound Society (BMUS), a national survey which has confirmed that most ultrasound services in the NHS cannot currently meet these requirements [9]. The Society of Radiographers has also called for a review of the implementation of CBv2 [10].

We have therefore developed a Care Pathway which can be implemented in two phases, according to Trust capacity. Phase I should be achievable with current resources, while sonographic services seek to acquire the additional training and resources required for Phase II. These Explanatory Notes are designed to be read in conjunction with Care Pathways I and II.

While we have made these recommendations as evidence based as possible, maternity care needs to be personalised and based on good clinical judgement. The Perinatal Institute and its staff cannot be held liable for any adverse outcome.

We are welcoming further comments **up to 12 December**, after consideration of which we intend to publish, in early January, the final Phase I and II versions for implementation in GAP units by April 2020.

A. Risk Assessment

- 1. Early pregnancy risk assessment and triage into the correct care pathway is essential. As the significance of risk factors is often determined by the severity of current and previous conditions and various other circumstances, moderate and high risk categories are amalgamated into an 'Increased risk' group which should undergo obstetric assessment to help determine the appropriate pathway and level of investigations and surveillance.
- 2. Previous 'SGA', if determined by customised centiles, is more likely to be due to fetal growth restriction (FGR) than if SGA is determined by population centiles on which CBv2 is based. It is therefore more likely to represent high risk and is often the only available indicator of the likelihood that there was indeed previous FGR. Obstetric review should consider severity, gestational age at onset (if known), gestational age at delivery and associated factors such as preeclampsia.

- 3. Previous stillbirth is considered an increased risk, regardless of size and stated cause, unless placental insufficiency has been reliably excluded by placental pathology examination.
- 4. Calculating an estimated fetal weight (EFW) at the anomaly scan is not recommended as good evidence is lacking about its efficacy to predict adverse outcome. Preliminary results presented at the 2019 Fetal Growth conference [11] suggest that the narrow normal range at 20-23 weeks can frequently lead to a false positive suspicion of SGA. The error is substantially increased with population based fetal weight standards. If units nevertheless wish to assess EFW at this time, we recommend use of the customised centile calculator which works from 20 weeks gestation and is available from the GAP Team on request.
- 5. For women with a history of, or significant risk factor for placental dysfunction (including history of pre-eclampsia or fetal growth restriction), Aspirin 75-150mg **nocte** is recommended from 12 weeks to birth according to the latest NICE guidelines [12].
- 6. We recommend that the increased risk group have an initial **obstetric review**, to determine next steps according to severity and unit policy.
 - **Phase 1**: Pregnancies considered high risk should be referred to maternal-fetal medicine (MFM) services, where available, for investigation and review:
 - if uterine artery (UtA) Doppler normal → moderate risk pathway;
 - if UtA Doppler abnormal continue under MFM surveillance

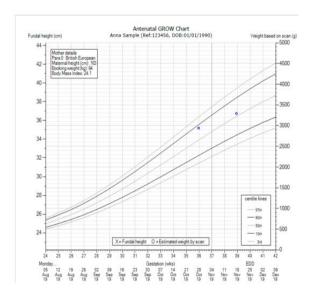
Where MFM services are not available, frequent assessment from 24 weeks throughout the third trimester is recommended, as per Care Pathway.

Phase 2: Pregnancies considered high risk can have UtA Doppler performed in the ultrasound department, with referral to MFM if abnormal.

B. Fetal growth surveillance

- The low risk pathway follows the existing algorithm, with 2-3 weekly clinical and fundal height assessment from 26-28 weeks until delivery according to unit policy, using a standardised technique [13] and with measurements plotted on the customised GROW chart. If suboptimal growth is suspected (first fundal height measurement <10th centile; or slow or static growth), direct referral for growth scan and Doppler is recommended.
- 2. Where SFH is unreliable because of high BMI (35+) or large or multiple fibroids [6], growth monitoring by serial ultrasound scan is indicated. Where resources allow, this should be done 3 weekly and starting from 28 weeks as this measurement serves as an important baseline for assessment of fetal growth during the third trimester.
- 3. Normal growth rate / velocity varies with gestational age and is highest in the middle of the third trimester. It also varies with the customised growth potential of each fetus. For example, the average (50th centile) velocity, expressed in grams per day (g/d), can range from 22g/d between 28-31 weeks in a small mother with a baby of expected term weight of 3100g, and 32g/d between 34-37 weeks for a larger mother expecting a baby weighing 3700 g, or 50% higher. Similarly, the 10th and 3rd centile growth rates shown on the GROW chart also vary with gestational age and expected birthweight.
- 4. Slow or static growth by **serial SFHs** is defined as a trajectory which is less (slower) than the slope of the curve / growth velocity indicated by the **10th centile line** on the customised chart <u>over the same gestational age interval</u>. The 10th centile is the appropriately sensitive screening tool to identify cases that need referral for ultrasound biometry.

- 5. Slow or static growth by **serial EFWs** is defined as a trajectory between scan measurements which is slower than the slope of the **3**rd **centile line** on the customised chart <u>over the same gestational age interval</u>. A growth rate less than the slope of the customised 3rd centile line predicts adverse perinatal outcome [14]. For precision and reduced effect of scan error, routine serial EFW measurements to assess growth velocity should be at least 3 weeks apart [7]. While third trimester EFW measurements in routine NHS practice have been shown to be accurate to within +/-10% in 70% of cases [15], consideration should be given to the clinical implication of potential scan error, as well as the overall need for quality assurance. The Perinatal Institute has developed a free audit tool for EFW error, available from the GAP team.
- 6. During 2020, we will be introducing auto-plotting and digital assessment in the GROW App, with alerts if the growth velocity is outside the normal range at the respective stage in pregnancy. In the interim, visual assessment is required, comparing serial SFH and EFW measurements with their respective 10th and 3rd centile reference lines. Plotting can be assisted by set-squares, available from the GAP Team. The figures below illustrate an example of manual assessment of growth rate.



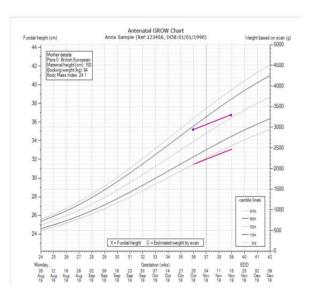


Fig 1 (left) has two sample EFW measurements plotted at 36 and 39 weeks, each measurement between the 50th and 90th centile but suggesting slow growth.

In Fig 2 (right), a line is drawn through the two plots to delineate the slope. Using a set square, a parallel line is drawn through the 3rd centile line over the same gestational age interval, which shows that the growth rate is slower than the lowest accepted rate in this pregnancy and over this gestation interval.

C. Further Investigation and Management

- 1. The Care Pathway outlines the suggested level of surveillance when placental insufficiency is suspected by an EFW <10th centile, or slow or static growth, with or without abnormal Dopplers. Fetal medicine involvement should be sought at early gestations, e.g. before 32-34 weeks.
- 2. In pregnancies with evidence of growth restriction (EFW<3rd centile and/or slow/static growth and/or abnormal Dopplers), delivery will be indicated by 37 completed weeks or earlier, according to severity and Doppler findings.
- 3. An EFW between the 3rd and 10th centile, on a customised chart adjusted for constitutional variation, is also associated with increased risk of adverse perinatal outcome if the pregnancy is continued at term. Concern about early term delivery because of an association with special educational needs

(SEN) in infancy and childhood [16] needs to be balanced by a significant increase of cerebral palsy risk in SGA babies delivered at term [17]. Furthermore, there is increasing risk of stillbirth until delivery, and the majority of deaths prevented since the introduction of GAP had late onset FGR in the 3^{rd} to 10^{th} centile band [18]. Consideration of timing of delivery should include uterine and middle cerebral artery Doppler findings: if all Dopplers are normal, expectant management to 39 weeks is likely to be safe [19]. When such a service is not available and growth restriction cannot be excluded (Phase I), earlier delivery (37 – 39 weeks) is advisable.

D. Audit

Ongoing audit of detection rates is essential to monitor and continue progress made. The GROW App will produce the following reports to assist units – quarterly or half yearly, depending on size of service:

- 1. Proportion of babies born <10th and <3rd centile
- 2. Antenatal detection rates of babies born <10th and <3rd centile
- 3. False positive detection rates of babies born <10th and <3rd centile

These reports will also include a national average comparison and a top 10-unit comparison. With unit approval, reports can also be produced for networks and regions.

Optional questions will be added in the GROW App in 2020 to enable units to undertake more thorough assessment of service provided and outcome achieved. The reports will include:

- Percentage of pregnancies identified as increased risk in early pregnancy and care offered
- Aspirin use and outcome
- Third trimester scan regime and outcome and in pregnancies with different risk factors

In addition, the GAP-SCORE tool will facilitate ongoing case-note review of 'missed' SGA (neonates with birthweight $<10^{th}$ and $<3^{rd}$ centile) that were not detected antenatally.

Conclusion

The new GAP Care Pathway introduces the main recommendations of version 2 of the Care Bundle while retaining and building on the key elements of the successful GAP algorithm and customised surveillance. The Care Pathway is presented in two phases, with Phase I for interim use while enhancing the training and resource requirements for Phase II.

Next steps

- 1. We have scheduled two initial WebEx sessions to demonstrate the new Care Pathway, with extended Q&A: 1. Wednesday 4th Dec., 11am-12noon; and 2. Tuesday 10th Dec., 11am-12 noon. If you wish to participate, please send details to gap@perinatal.org.uk and specify preferred date.
- 2. The Perinatal Institute's regular, free GAP on-site workshops will henceforth include focussed training on the new GAP Care Pathway; to register: https://www.perinatal.org.uk/diary/gapbookingform.aspx
- 3. We are holding two consecutive 'Ultrasound and Doppler Masterclasses' for sonographers including live demonstrations on 2nd and 3rd December. These are fully booked but if there is sufficient interest, may be repeated in the New Year.
- 4. We are developing focussed e-learning and certification courses for sonographers details to be announced soon.
- 5. We are working with BMUS who is represented on a Health Education England Task Force to address training and resource needs associated with CBv2.

References

- 1. Saving Babies' Lives v.2: A care bundle for reducing perinatal mortality. NHS England, 2019 www.england.nhs.uk/publication/saving-babies-lives-version-two-a-care-bundle-for-reducing-perinatal-mortality
- Gardosi J, Giddings S, Clifford S, Wood L, Francis A. Association between reduced stillbirth rates in England and regional uptake of accreditation training in customised fetal growth assessment. BMJ Open 2013;3(12). https://bmjopen.bmj.com/content/bmjopen/3/12/e003942.full.pdf
- 3. Widdows K, Roberts S, Camacho E, Heazell A. Evaluation of the implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England (SPIRE) Manchester, UK: Maternal and Fetal Health Research Centre, University of Manchester; 2018 https://bit.ly/2LZFbBv
- 4. Williams M, Turner S, Butler E, Gardosi J. Fetal growth surveillance current guidelines, practices and challenges. Ultrasound 2018 https://bit.ly/2XKypZB
- Gardosi J, Francis A. Controlled trial of fundal height measurement plotted on customised antenatal growth charts. Br J Obstet Gynaecol. 1999;106(4):309–317 https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/j.1471-0528.1999.tb08267.x
- 6. Clifford S, Giddings S, Southam M, Williams M, Gardosi J. The Growth Assessment Protocol: a national programme to improve patient safety in maternity care. MIDIRS Digest. 2013;23:516–23 https://bit.ly/2Do0tGw
- 7. RCOG. The investigation and management of the small-for-gestational-age fetus. Green Top Guideline 31. RCOG 2013 https://www.rcog.org.uk/globalassets/documents/guidelines/gtg 31.pdf
- Jayawardena L, Sheehan P. Introduction of a customised growth chart protocol increased detection of small for gestational age pregnancies in a tertiary Melbourne hospital. Aust N Z J Obstet Gynaecol. 2018 https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/ajo.12902
- 9. Survey of ultrasound and Doppler services. Perinatal Institute and BMUS, 2019 https://bit.ly/20pZHPt
- 10. Society of Radiographers. SCoR calls for review of the implementation of Saving Babies' Lives Care Bundle V2 2019 https://www.sor.org/news/scor-calls-review-implementation-saving-babies-lives-care-bundle-v2
- Hugh O, Francis A, Gardosi J. Customised vs population based fetal weight standards to define small for gestational age as a risk factor at 22 weeks gestation. 8th International Conference of Fetal Growth, Berlin 2019 www.fetalgrowth.org Abstract PO8 https://bit.ly/2XQuiZH
- 12. National Institute for Health and Care Excellence. Hypertension in pregnancy: diagnosis and management (Clinical Guideline 133). NICE 2019 www.nice.org.uk/guidance/ng133
- 13. Morse K, Williams A, Gardosi J. Fetal growth screening by fundal height measurement.

 Best Practice Research Clin Obstet Gynaecol. 2009;23(6):809–18. https://bit.ly/327QJLM
- 14. Francis A, Hugh O, Gardosi J. Slow growth defined by customised growth trajectory and adverse perinatal outcome. 8th International Conference of Fetal Growth, Berlin 2019 (www.fetalgrowth.org) Abstract O4.3 https://bit.ly/2KZHJBa
- 15. Francis A, Tonks A, Gardosi J. Accuracy of ultrasound estimation of fetal weight at term. ADC Fetal and Neonatal https://fn.bmj.com/content/96/Suppl 1/Fa61.1
- 16. MacKay DF, Smith GCS, Dobbie R, Pell JP. Gestational Age at Delivery and Special Educational Need: Retrospective Cohort Study of 407,503 Schoolchildren. PLoS Med. 2010 Jun 8;7(6):e1000289 https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000289
- 17. Jacobsson B, Ahlin K, Francis A, Hagberg G, Hagberg H, Gardosi J. Cerebral palsy and restricted growth status at birth: population-based case-control study. Br J Obstet Gynaecol. 2008 Sep;115(10):1250–5 https://obgyn.onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2008.01827.x
- 18. Williams M, Turner S, Hugh O, Gardosi J. Reduction of small-for-gestational-age stillbirths at term in the GAP programme 2015-2018. Br J Obstet Gynaecol. 2019;126(S2):53. https://bit.ly/2YxH7a5
- 19. Figueras F, Gratacos E. An integrated approach to fetal growth restriction. Best Practice Research Clin Obstet Gynaecol 2017;38:48-58. https://bit.ly/2XevtA5