Submission to the Senate Select Committee on Stillbirth Research and Education

31 August 2018

Dear Committee,

Thank you for this opportunity to make a submission to this very timely public enquiry.

The Perinatal Institute seeks to address stillbirth risk and quality of care through a variety of avenues, as outlined in the Introduction. Our submission focuses on the prevention of avoidable stillbirths associated with unrecognised intrauterine growth restriction. This is a major, ongoing effort by our multi-professional team, working with front line maternity service staff in the UK and internationally.

We hope our contribution will be considered useful in your deliberations.

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Summary

This submission outlines the background and progress of a stillbirth prevention programme developed by the Perinatal Institute, starting in the West Midlands, UK. Through a series of detailed case reviews as well as analysis of regional maternity data, we established the now widely accepted fact that the majority of normally formed fetal deaths are preventable through better antenatal recognition of fetal growth restriction. We then developed a comprehensive training and audit programme (GAP) with customised growth charts (GROW) to improve obstetricians', midwives' and ultrasonographers' confidence in antenatal assessment.

After successful regional pilots, GAP has since been implemented in over 80% of hospitals in the UK national health service (NHS) and is credited with the year on year drop in stillbirth rates in England over the last 6 years, equivalent to a 23% reduction compared to the preceding 10 year average. Pilots of the GAP programme adapted to New Zealand have also shown encouraging results, and the Institute has recently been commissioned to proceed there with a national roll out.

An Australian version of customised charts has also been produced to reflect this country's multi-ethnic population. The GROW chart and centile calculators are already used by an increasing number of clinicians in different States, and there is evidence emerging here too that they help to improve the antenatal identification of babies at risk due to fetal growth restriction. However a significant and sustained impact on stillbirth prevention will require a co-ordinated, intensive yet affordable programme, modelled on experience elsewhere and adapted to Australian circumstances.

Introduction

The Perinatal Institute is a multidisciplinary, not-for-profit organisation based in Birmingham, UK, established in 2000 with the central mission to understand the causes of adverse perinatal outcome and to implement strategies for prevention. Initially hosted and funded by the National Health Service (NHS) in the West Midlands, it became an independent organisation in 2013 and now receives its main funding through service contracts with most NHS Trusts and Health Boards in England, Wales, Scotland, and Northern Ireland. It also has many international collaborations.

The Institute has a tradition of working with front line clinicians as well charities representing bereaved parents, and are eager to learn from their experience. In 2007 we hosted the 3rd Congress of the International Stillbirth Alliance together with SANDS-UK, and introduced parallel streams for parents and clinicians/scientists, with joint sessions to raise awareness of the impact of stillbirth on families and to identify priorities for research and service development www.pi.nhs.uk/isa2007/welcome.htm.

Our products and services aim to enhance the quality and safety of maternity care as well as patient autonomy and engagement. They include

- the national hand-held maternity notes www.preg.info, used in the majority of maternity units in England; they
    - provide prompts for the care provider re standard of care, and information for the mother, her partner and family about available choices;
    - detail what to expect at the various stages in pregnancy and the postnatal period, highlight risks to mother and baby including risk factors for stillbirth, and what to look out for- e.g. changes in the pattern of fetal movements;
    - require the care providers to sign to confirm that relevant information has been discussed at the respective visits;
    - provide information in several languages;
    - use standardised definitions of maternity data including ethnic origin, thereby facilitating accurate collection of data.
- The suite of maternity notes includes the Postnatal Bereavement Notes, designed to help ensure the provision of appropriate investigations and explanations after a perinatal loss, with language sensitive to the circumstances. www.preg.info/PostnatalBereavementNotes/
- The same principle of 'mother in control of her own record' is being applied to the electronic version, the Mothers Information Application (MiApp; www.perinatal.org.uk/miapp), which will be launched in 2019. MiApp will be able to link to any primary and secondary information system, and will be available in multiple languages.
- Perinatal mortality review software and training for objective, standardised assessment of care following stillbirth or neonatal death (SCOR – standardised clinical outcome reviews; www.perinatal.org.uk/scor/)- an internationally validated tool which helps clinicians to learn from mistakes, facilitates peer review to identify system errors, and helps to formulate action plans.
- Customised growth charts and the associated Growth Assessment Protocol (GAP), www.perinatal.org.uk/FetalGrowth/GAP/ - a comprehensive training and audit programme, responsible for the recent year on year drop in stillbirth rates in England.

Our submission will focus on this last element as **one that could make an instant impact on stillbirth rates in Australia**, as it has the evidence base and track record and is available for immediate local, state-wide or national implementation.

Background: Fetal growth and stillbirth

When we started this work in the early 2000s, the stillbirth rates reported by the UK Office of National Statistics (ONS) were unchanged over the last 20 years, and the rate for the West Midlands was consistently one of the highest in the country. The majority of stillbirths were categorised as 'unexplained', even if a postmortem had been performed. This was not helpful for mothers trying to come to terms with their loss, clinicians trying to understand what went wrong, and commissioners of maternity services seeking to improve safety. In an invited commentary on the 8th report of CESDI (Confidential Enquiry into Stillbirths and Deaths in Infancy, England and Wales 2001), which had once again reported a high rate of 'unexplained' stillbirths, we set out the argument that there is a need to improve classification systems, and to get away from the mindset that 'unexplained' equals 'unavoidable'. [1]

After conducting several series of confidential enquiries (independent panel reviews of anonymised case notes), it became apparent that many stillbirths (counted from 24 weeks in the UK) occurred after intrauterine growth restriction which had not been recognised. Conventional classification systems often failed to record this, as they either had no category for smallness for gestational age (SGA) or had to rely on antenatal recognition. Furthermore, pathologists tended to use inappropriate weight standards for assessment of weight at postmortem [2]. Thus growth restriction was often missed antenatally, with severe consequences, and again postnatally, when the case was assessed.

We therefore developed a new classification [3] which could rely also on assessment of the birthweight of the stillborn, adjusted for an average delay from intrauterine demise to delivery. The emphasis was not only on finding a 'cause' – which was often unrecognised 'placental insufficiency'– but a clinically relevant 'condition' that can be acted on, like an SGA fetus. This approach found that the majority of hitherto 'unexplained' deaths were in fact babies that had not fulfilled their growth potential [3].

We subsequently applied this classification to a large NHS dataset [4], and found that

1. compared to all other risk factors including social deprivation, smoking, obesity etc, being SGA in utero was the single strongest risk factor to the fetus, and represented a 7-fold increased chance of the baby dying before delivery;
2. lack of antenatal identification that the fetus is SGA approximately doubles this risk; whereas
3. antenatal recognition that the fetus is SGA halves its risk by providing the option of elective delivery, and results in an average reduction in gestation length by only 10 days, from 40 to 38.5 weeks; this is because most of these cases represent 'late onset' growth restriction, with placental function not keeping up with the increasing demand of the growing fetus.

Customised growth charts

These findings needed to be seen in the context of evidence that only 15-20% of SGA babies were usually detected as such antenatally [5]; in essence, our health system failed to identify the most common and most avoidable risk of stillbirth. A key issue we needed to address was to increase clinicians' confidence in their tools, and in particular the growth charts used for surveillance; too often the measurement of fetal size – assessed by fundal height measurement or by ultrasound biometry – was not trusted because of the normal or 'constitutional' variation in a heterogeneous population.

We therefore developed a computer generated customised chart that was individually adjusted for each pregnancy, according to a set of variables that proved to be significant in influencing the growth and birthweight of the baby: maternal height, maternal weight at booking, her parity (birth order) and

ethnic origin as well as the sex of the baby if known [6,7]. The chart provided optimal curves for fetal weight that should be achievable in optimal circumstances during an uncomplicated pregnancy (Gestational Related Optimal Weight, GROW). The model does not seek to adjust for pathological factors – such as smoking or diabetes - so that if these factors are present and affect fetal growth, they are more easily recognised.

Birthweight and fetal weight centiles calculated by this method have been found to be better at detecting pathology and abnormal outcome, thereby increasing the ability to detect when growth is / has been abnormal. A large number of studies have investigated the use of customised standards, compared them with conventional, population based charts and found 'customised SGA' to be more closely related to adverse outcomes such as stillbirth and neonatal death, as well as various indicators of perinatal morbidity. Rather than listing them all here, they are reviewed in a recent article which is available to download [8]. The review includes studies that have not found customisation of benefit.

The recently widely promoted multinational Intergrowth 21st standard with a 'one size fits all' approach [9,10] has been contradicted by the subsequent multinational WHO study [11,12] as well as country specific studies in New Zealand, Hong Kong and England [13–15], and a 10 country comparison with 1.2 million births conducted by the Perinatal Institute, which found that customised definition of SGA identified significantly more babies at risk of stillbirth [16].

Customised charts also confirm normality, thereby reducing 'false alarms' causing unnecessary anxiety investigations and intervention. [17] This is of particular relevance to subgroups of the population that are considered at risk because their babies are (normally) smaller, such as mothers from some ethnic groups. For example mothers of South Asian origin in England, when managed by a population based standard, undergo unnecessary investigations and interventions [18] while the babies identified as small but normal when customising for their ethnic group do not have an increased mortality risk [19].

GROW charts also improve the identification of large for gestational age (LGA) babies at risk of adverse outcome [20,21], and are being used in the currently recruiting, UK wide, NIHR funded randomised trial on the prevention of shoulder dystocia.

Customised birthweight centiles and antenatal charts are recommended by Royal College of Obstetricians and Gynaecologist (RCOG) guidelines for the assessment of SGA [22]. The GROW software now includes over 120 ethnic or country of origin coefficients derived from 3.7 million births from 28 countries. It is provided freely as individual and bulk centile calculators to clinicians and researchers to assess fetal weight and birthweight, and as growth charts with appropriate training.

The Growth Assessment Protocol (GAP)

GAP is a comprehensive programme which includes

- training in principles of customised charts and their use to assess size and growth
- training in standardised fundal height measurement and plotting
- clear guidelines and referral protocols for further investigation
- audit tools to assess detection rates and automated reporting (local and regional)
- GAP – SCORE audit tool and training for missed cases (undetected SGA)
- Audit tool to assess ultrasound measurement error in estimated fetal weight (EFW)
- E-learning (theoretical and practical modules) with test and accreditation
- ongoing helpdesk support for front line clinicians and hospital IT staff

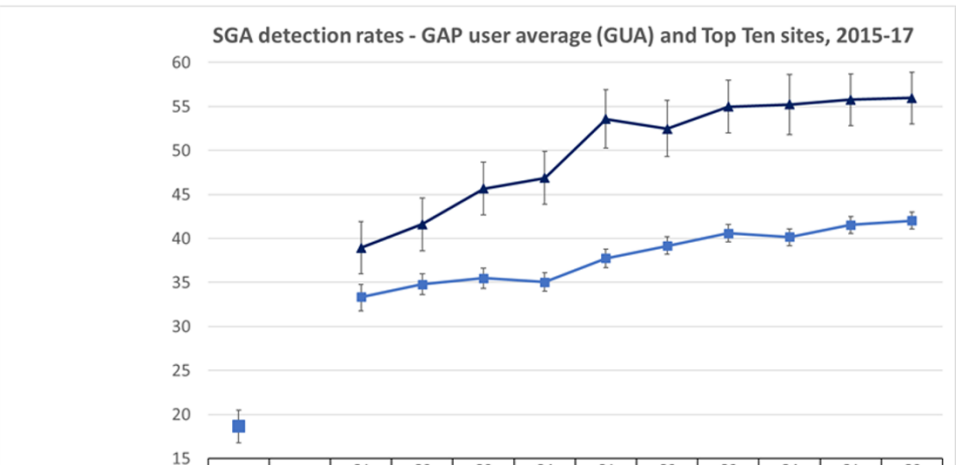
We developed an algorithm with a list of risk factors, the presence of which determine the care pathway (low risk: serial fundal height measurement; increased risk: serial growth scans). NHS England have since adopted a similar algorithm for the 'Fetal Growth' element of the Saving Babies' Lives Care Bundle [23].

Effect on detection of SGA

An initial controlled study [24] found that training in fundal height measurements and plotting on customised charts significantly improves the antenatal detection of SGA as well as LGA babies. In addition, the use of customised charts significantly reduced false positive referrals and resulted in fewer unnecessary investigations and patient anxiety.

Since then, evaluation in practice has confirmed that implementation of GAP increases detection rates [25]. We successfully argued for adoption of antenatal detection of SGA as a performance indicator within the NHS England Saving Babies' Lives Care Bundle [23]. The GROW software facilitates recording of pregnancy outcome, produces the birthweight centile, and provides an automated report of referral and detection rates for local clinicians and networks.

Before implementation, maternity units are asked to undertake a baseline audit of their antenatal detection rate of babies that are SGA at birth (defined as below the 10th customised centile). This averages 18.7%, with a range of 12-22%. Following implementation, detection rates increased 2-3 fold to the current national average of 42% - which, with further training and local effort, reaches an average of 56 % in the most engaged units [8,26] (Fig 1)



	Baseline		Q1 2015/16	Q2 2015/16	Q3 2015/16	Q4 2015/16	Q1 2016/17	Q2 2016/17	Q3 2016/17	Q4 2016/17	Q1 2017/18	Q2 2017/18
GUA Detection Rate	18.7		33.3	34.8	35.5	35.0	37.8	39.2	40.6	40.2	41.6	42.0
Top Ten Detection Rate			38.9	41.6	45.7	46.9	53.6	52.5	55.0	55.2	55.8	56.0
Cases - GAP User Average	13,844		27,414	43,406	53,233	56,393	65,455	73,360	74,774	77,507	83,388	92,112
Cases - Top Ten Average			7,535	7,876	8,806	8,927	8,174	11,200	11,424	10,844	12,884	8,388

Fig 1. Antenatal detection of SGA in the GAP programme [8]. Baseline rates, GAP user average (GUA) and top ten performing units are shown.

This improvement, although far from the desired 100%, seems to detect the most at-risk pregnancies, many of which were considered low risk at the beginning of pregnancy. The longitudinal surveillance also helps to identify pregnancies at risk because of slow growth without the fetus being SGA.

Missed case audit

This part of the GAP package focusses on the analysis of cases that were NOT detected antenatally, to try to ascertain the reasons, whether they relate to training, protocols, or service provision. Clinicians are asked to enter a random selection of cases into a bespoke computer programme (GAP-SCORE) which takes them through a set of questions and then produces a case summary and trend analysis of the main 'themes'.

A recently published [26] summary of just under 3000 of such missed cases (Figure 2) shows that the largest category were instances where the pregnancy was acknowledged to be high risk and required serial scanning, but the fact that the fetus was SGA was still missed. In many instances this occurs because the serial scanning protocol was not followed – e.g. (the largest category): insufficient number of scans, or stopping serial assessment before term.

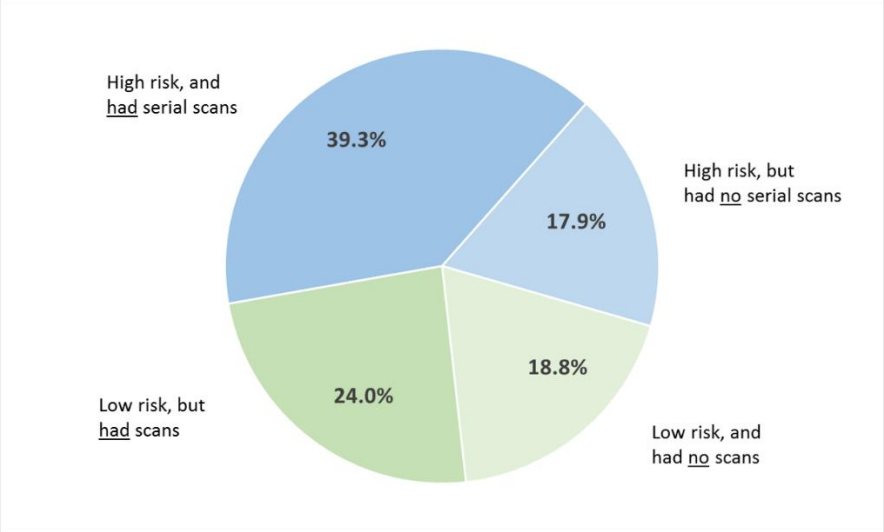
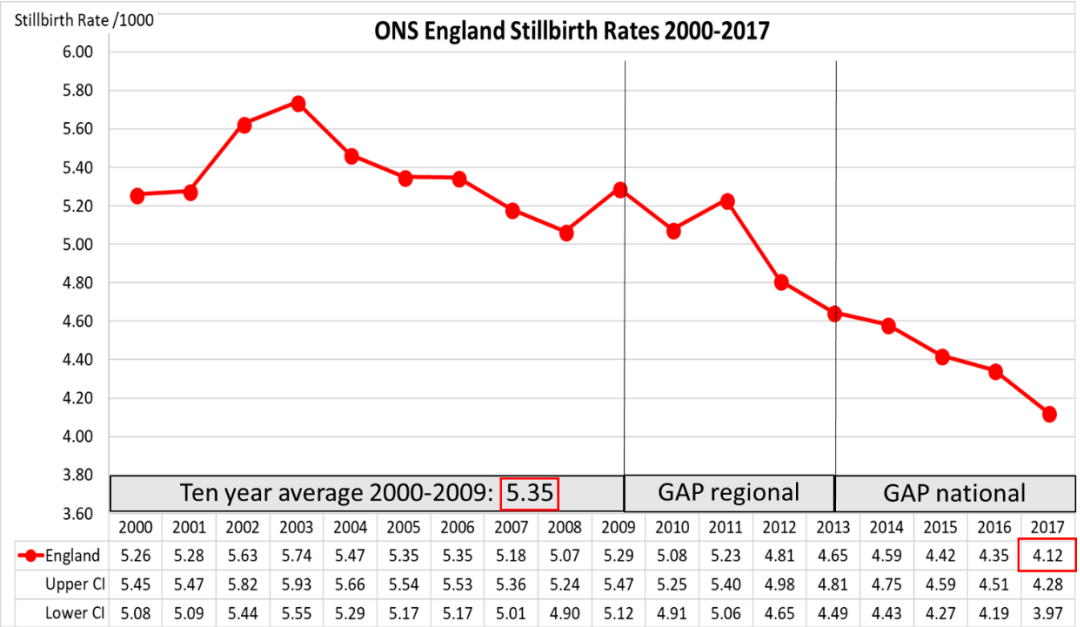


Fig 2. Missed case audit of 2977 pregnancies with SGA newborn not detected antenatally, from 64 Trusts and Health Boards in the UK GAP programme [26].

Effect on stillbirth rates

GAP was initially implemented in the West Midlands in 2009, and within 3 years reduced the stillbirth rate to below the national average for the first time since records began 50 years earlier [27]. It was then also rolled out in two other NHS regions, and again stillbirth rates reduced there while stagnating in the non-participating regions [28,29].

This regional reduction started to positively affect also stillbirth rates in England, which was reinforced by the subsequent national roll-out from 2013, and has since resulted in the continued, year on year fall in ONS stillbirth rates to 4.12 (Fig 3). This drop from the previous 10-year average of 5.35 amounts to a reduction by 23% and is equivalent to approximately 860 fewer deaths in England per year.



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
England	5.26	5.28	5.63	5.74	5.47	5.35	5.35	5.18	5.07	5.29	5.08	5.23	4.81	4.65	4.59	4.42	4.35	4.12
Upper CI	5.45	5.47	5.82	5.93	5.66	5.54	5.53	5.36	5.24	5.47	5.25	5.40	4.98	4.81	4.75	4.59	4.51	4.28
Lower CI	5.08	5.09	5.44	5.55	5.29	5.17	5.17	5.01	4.90	5.12	4.91	5.06	4.65	4.49	4.43	4.27	4.19	3.97

Fig 3 Trend in stillbirth rates in England, before and after the introduction of the GAP programme. Source: Office of National Statistics [30]

Uptake and Implementation

Current uptake across the UK extends to 127 of the 157 (81%) NHS Trusts and Health Boards. We publish the GAP status of hospitals (http://www.perinatal.org.uk/gap-uptake.aspx)as we get regular enquiries from expectant parents wanting to know whether the hospital they intend to book at is in the GAP programme.

Implementation is supported by intensive, multidisciplinary unit- and regional network based train-the-trainer workshops with remote follow-up support. The most rapid and effective progress occurred when short term secondments of designated clinical midwives (DCMs) were NHS funded to co-ordinate local training and implementation of charts, protocols and care pathways, as was the case in our 'Saving Babies in North England' (SABINE) project in 2015. [31]

Uptake in Wales followed an Inquiry into Stillbirths by the Health and Social Care Committee of the Welsh Assembly (2012); this led to the Welsh Initiative for Stillbirth Reduction (WISR) [32] which promoted the GAP programme to address detection of growth restriction as a key element. GAP has since been implemented in all Welsh Health Boards and average detection rate has come to the UK average. In Northern Ireland, a quality improvement programme promoted GAP uptake and audit as clinical network which proved very effective and resulted in detection rates well above the national average.

In Scotland, GAP was implemented in 2014 in 12 of its 14 Health Boards (86%), as part of a nationally commissioned program, while also benefitting from a pre-existing quality improvement initiative in maternity. Its own 10-year (2000-2009) average stillbirth rate of 5.41 dropped similarly, to 4.24/1000 in 2017, representing a 22% reduction.

In England, GAP is now aligned to the Saving Babies' Lives Care Bundle launched in 2016 [23] which uses a version of the GAP algorithm for risk assessment and referral pathway, as well as detection rates of SGA as key audit measures. A recently completed independent report for NHS England [33] included an analysis of the Fetal Growth element of the care bundle in 19 NHS Trusts, 15 of which were in the GAP

programme. The investigators reported significantly improved compliance with use and plotting on growth charts, an increase in antenatal detection of SGA and a 31% reduction in SGA stillbirths [33].

Our roll-out programme has benefited from awareness raising supported by charities including SANDS-UK and Tommy's, and in particular the national 'Made to Measure' campaign by the MAMA Academy, a charity founded by a bereaved mother with an 'unexplained' stillbirth with unrecognised fetal growth restriction. Implementation was also assisted by publicity following awards received for our prevention programme (www.perinatal.org.uk/awards) including Patient Safety Awards in 2013, 2014 and 2015, the BMJ Award for clinical leadership (2015), a Queen's Award (Enterprise/Innovation; 2016) for reducing stillbirths, and a Princess Royal Training Award (2018) for training and education.

International application

The Perinatal Institute is founder and co-organiser of the annual International Conference of Fetal Growth, with this year's 7th meeting in Milan (www.fetalgrowth.org) again aiming to facilitate critical evaluation of the latest evidence on fetal growth surveillance strategies to reduce adverse outcomes.

The customised standard is individual, not country specific, and hence has validity across borders. The birthweight of a baby of a standard size mother of Anglo-European origin is virtually the same whether she is in England, USA, Australia or New Zealand [34]. Similarly, the weight of a baby of a low risk Indian mother in Hyderabad is the same as that of a low risk mother of Indian origin in England [35].

International application of the customised chart principle is facilitated by local champions who make significant efforts to provide us with datasets from which we can derive coefficients for their country. Based on 3.7 million birth data collected from 28 countries to date, we have been able to develop the 'Global GROW App' with coefficients for over 120 ethnic groups. We provide bulk centile calculators on request (300 over the last three years alone) to support a wide range of projects, and customised assessment has become the new standard for research related to fetal and neonatal weight.

In the Netherlands the Royal Dutch Midwifery Association (KNOV) have acquired a national license of GROW NL for all their members, and there is now interest in several European countries to implement GROW charts and associated GAP training.

In New Zealand, we collaborated with Prof Lesley McCowan and team from the National Women's Hospital to derive coefficients for a customised growth and birthweight standard for their multi-ethnic population [36], since updated [37]. This standard has been usefully applied to identify SGA in diabetic populations [38] and found to be significantly better in identifying pregnancies at risk compared to the Intergrowth 21st 'one-size-fits all' standard [13], since confirmed in other populations [16].

GROW NZ and elements of GAP training have started to be piloted several years ago in some District Health Boards and practices of several hundred Lead Maternity Carers (LMCs). The free service included training workshops led by local specialist midwives trained by the Perinatal Institute, andh e-learning support. The pilots have been successful and have been credited with a reduction in SGA stillbirths, as per the 2018 report of the Perinatal and Maternal Review Committee (PMMRC) [39].

Customised charts have been endorsed by the RANZCOG and the New Zealand Ministry of Health. The Obstetric and Related Medical Services' national referral guidelines require use of a customised chart when referring women with suspected SGA, and are endorsed by the PMMRC and the District Health Board Clinical Directors. The New Zealand Accident Compensation Corporation (ACC) has earlier this year commissioned the Perinatal Institute to roll out GAP training across the whole country in a three-year programme, with the option for continued funding subsequently through the government's new maternity programme under current development.

Australia

We have also collaborated with Australian clinicians and researchers to identify suitable databases to derive a customised standard for the Australian population [40], recently enhanced to 9 ethnic groups including Aboriginal and Torres Strait Islanders.

We have provided Australian versions of the bulk centile calculator to 106 researchers over the last three years, for studies requiring precise birthweight analysis, with topics ranging from assessing the effects diabetes or maternal asthma, to new biomarkers for fetal growth.

There is also an increasing interest in clinical application, with 20 registered sites to date – from individual clinics to tertiary centres, who together already generate 40,000 antenatal GROW charts a year. The map summarises the current distribution of charts and other GROW tools.

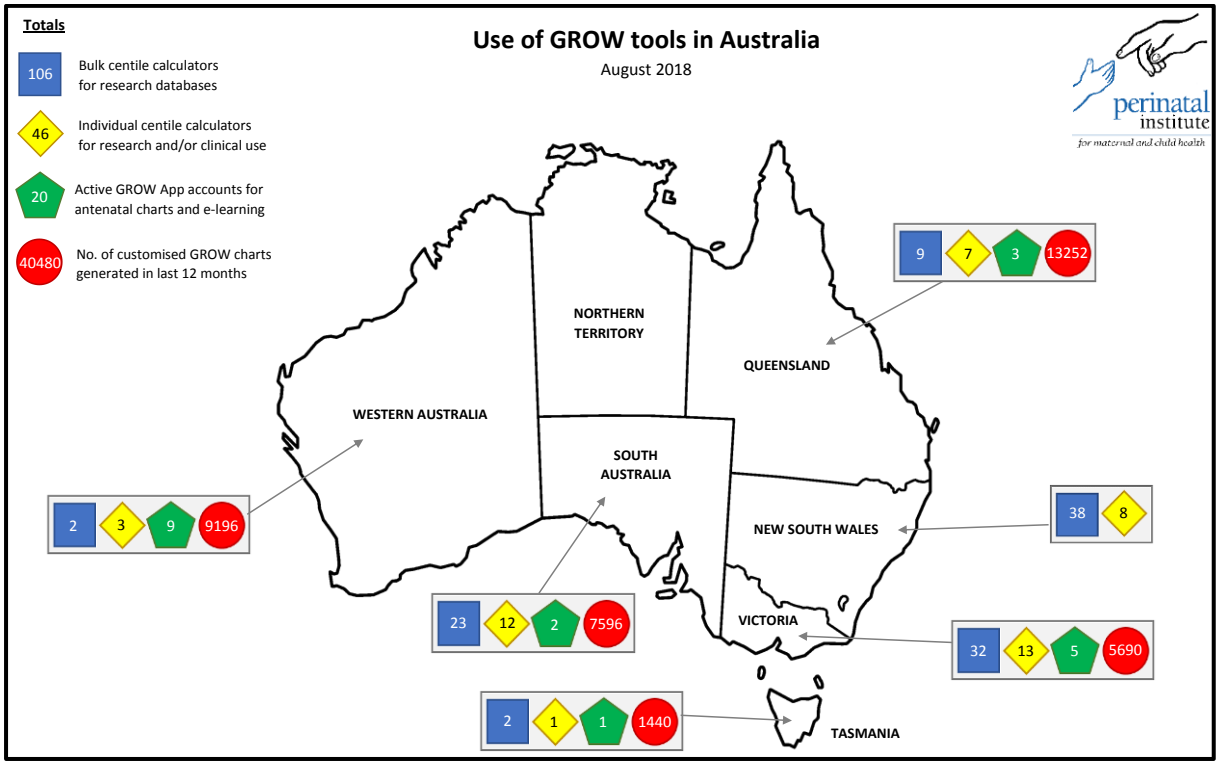


Fig 4. Use of GROW charts and associated tools in Australia - August 2018

Evaluations we are aware of to date have come from 1. Lyell McEwin Hospital in South Australia where customised charts showed a significant increase in antenatal referral of SGA babies [41]; 2. St John of God Hospital in Western Australia, where implementation of GAP has led to improved SGA detection as well as a reduction in stillbirths (Adj Professor Chris Griffin, Medical Director, Stateside Support Unit - personal communication) and 3. Melbourne Women's Hospital, where a formally evaluated pilot showed a significant increase in SGA detection [42] to levels similar to the UK, and resulted in the unit's recent decision to fully implement GAP.

However as far as we are aware there has been no wider interest to agree on a common standard for fetal growth, or to establish, or adopt, evidence-based algorithms and referral pathways. We submit that, considering what is already known about this most frequent cause of adverse pregnancy outcome, and how easily avoidable it often is, there is a need for a co-ordinated, focussed effort, and we would be pleased to assist in any such endeavour

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