Written evidence submitted by the Perinatal Institute (MSE0107)

Summary

Prevention of avoidable stillbirths is an important indicator of the safety and quality of maternity care. A focus on fetal growth and wellbeing has led to better outcomes as well as greater awareness on how to continue to achieve further improvements. However, such advances need to be supported with the provision of adequate training and resources, and a renewed emphasis on addressing inequalities and the service needs of a heterogeneous maternity population.

About us

The Perinatal Institute is a not-for-profit social enterprise, established in 2013 by core staff from its fore-runner, the NHS hosted West Midlands Perinatal Institute. We partner with the majority of NHS Trusts and Health Boards in the UK, providing various products (e.g. maternity records, charts, software) and services (training, analysis, reporting) to help improve safety and quality of maternity care. Our work has been recognised by a number of Awards for patient safety, training and clinical leadership, and the 2020 HSJ Partnership Award for 'Best Not For Profit Working in Partnership with the NHS'.

This submission

Our contribution focusses on prevention of antepartum fetal deaths, i.e. the 90% of all stillbirths that occur before the onset of labour and delivery.

We present our perspective on the following points in the Committee's call for evidence:

A. The impact of work which has already taken place aimed at improving maternity safety (Point 1);
B. Effectiveness of training and support offered to maternity staff (Point 4); and
C. What improvements could be made (Point 4).

A. Impact of work which has already taken place aimed at improving maternity safety

1. The Perinatal Institute's work builds on evidence it established as its West Midlands forerunner. National stillbirth rates had changed little over the preceding 20 years and were among the highest in Europe, and our regional stillbirth rates were amongst the highest in England. We were tasked with improving understanding of the causes and developing strategies for prevention.

2. The first problem was that the majority of stillbirths were kept being reported as 'unexplained', even if a postmortem had been performed. This was not helpful for mothers trying to come to terms with their loss, clinicians seeking to understand and address what went wrong, and commissioners seeking to improve patient safety. In an invited commentary in the 8th CESDI report, we set out the need to get away from the mindset that 'unexplained' means 'unavoidable'.

3. We undertook a series of regional confidential enquiries [2] which consistently showed that the majority of perinatal deaths had substandard antenatal care and were potentially avoidable. We also found that hospital based reviews failed to identify concerns in about three-quarter of cases. [3] This led to the development of the SCOR system (standardised clinical outcome reviews) [4][5] which facilitated the process and could also be used with external peer review.

4. Case reviews of antepartum stillbirths often revealed a failure to recognise and act on a fetus' failure to grow, and pointed to a variety of system issues including risk assessment and subsequent management planning, measurement, growth charts, scan protocols and referral pathways [6]

5. Inclusion of a small for gestational age (SGA) category as a proxy for growth restriction in the analysis of regional antepartum stillbirths showed that the majority of hitherto 'unexplained' deaths were in fact babies that had not fulfilled their growth potential. [7]

6. A subsequent large population based study in the West Midlands found that, compared to all other risk factors including social deprivation, smoking and obesity, fetal growth restriction was the single strongest risk factor and represented a 7-fold increased risk of intrauterine death. Furthermore, lack of antenatal detection doubled this risk. [8]

7. Based on these insights, we devised a programme, the Growth Assessment Protocol (GAP), as a package with multidisciplinary training in risk assessment, standardised measurement and plotting, customised antenatal growth charts, referral algorithms and audit tools. [9]

B. Effectiveness of training and support offered to maternity staff

8. The programme was implemented through a series of midwifery training workshops in the West Midlands and two other English regions and resulted in a significant decline in stillbirth rates in these three regions, while the remaining NHS regions in England showed no change. [10]

9. The roll-out was then continued on a national level in England and all home countries, with GAP licensed to individual Trusts and Health Boards at an approx. cost of 50 pence per pregnancy, and occasionally pump primed regionally (NHS North of England, 2015) or nationally (Scotland, 2015/6).

10. Training workshops were held by the GAP team with central, regional and local multidisciplinary accreditation workshops, backed up by theoretical and practical e-learning modules. The content included RCOG risk assessment, customised growth charts, GAP care pathway, and rolling audit.

11. The most consequential measure of performance was the antenatal detection of the small for gestational age baby which allows the undertaking of further investigation and informed timing of delivery. The programme is consistently achieving a 2-3 fold increase in detection rates, with acceptable false positive rates, and also improves detection of babies that are not SGA but have still failed to reach their growth potential.

12. The GAP algorithm became the template for the 'Fetal Growth' element of NHS England's Saving Babies Lives Care Bundle (2015/6), and the GAP team supported its development and roll-out.

13. Awareness of a fetus' growth status is also important for surveillance and management in labour, as growth restricted babies have diminished reserve and are more prone to develop fetal distress.

14. The programme includes automated, unit level reporting to help clinicians monitor and benchmark performance against national averages, and audit tools to investigate near misses, i.e. where a small fetus was not detected antenatally. There is helpdesk support which deals with protocol, guideline and technical enquiries, and support for struggling units by offer of advice and further training.

15. Despite an absence of a clear national endorsement, 81% of UK Trusts and Health Boards (78% following mergers) have implemented the programme to date [11], with over 600,000 pregnancies a year being managed in GAP units.

16. Since national roll-out there has been a year on year decline in stillbirths in England to its lowest ever level in (3.83/1000 in 2019) which represents a 28.4% reduction compared to the 2000-2009 average of 5.35/1000. [12]

17. However, level of adherence to the protocol varies in light of competing local priorities, shortages of staff and resources. A thorough investigation of unit level ONS data in England [13] (which won our statistician an [ONS Research Excellence Award)](), showed firstly an overall decline in stillbirths from 2012/3 observed in non-GAP units; this was possibly associated with a general increase in awareness, including publication in 2012 of the NHS Outcomes Framework [14] which included stillbirth as an outcome indicator; research papers highlighting the strength of association with fetal growth restriction [8]; and the new RCOG guidelines on the investigation and management of the SGA fetus [15]. Units nominally in the GAP programme but not following the surveillance protocol had similar rates; while those with full implementation and adherence to GAP guidelines had a significantly steeper decline n stillbirth rates. The largest drop was in the maternity units with the best antenatal detection rates, with a 24% reduction in stillbirths compared to non-GAP units.

18. The aforementioned 24% reduction in stillbirth rate, 1 death in 1000 births, if extrapolated to the latest (2019) ONS birth rate of 612,851 in England, is equivalent to the prevention of over 600 stillbirths per year - and therefore demonstrably achievable by upscaling antenatal detection of SGA.

19. While it is impossible to estimate, nay fathom, the magnitude of loss to the parents, the cost of a stillbirth to the health service and society can be estimated, as in a study [16] commissioned by the Stillbirth Foundation of Australia. They reached a figure equivalent to £ 34,000 Sterling per case, which included direct costs (health service, investigations, counselling; ca. £8,000) and indirect costs (funeral, absenteeism, loss of productivity; ca. £ 26,000). According to this figure, 600 fewer stillbirths would represent a saving of over £ 20 million per year.

20. Such 'savings' need to be offset against the cost of increased investigations and interventions. However diagnostic methods including ultrasound and Doppler are constantly improving in their ability to help determine the optimal time for delivery, once a problem is suspected. [16]

21. **COVID-19:** As in all health services, the pandemic has affected maternity and antenatal care, and RCOG/RCM as well as NHS England have issued recommendations on antenatal visits and investigations. A telephone survey of a random sample of maternity units in the GAP programme

in England confirmed fewer and shorter face to face appointments, but mostly in early pregnancy; and reduced access to ultrasound services while still maintaining key elements of the growth assessment protocol including serial scans in high risk pregnancy. Preliminary, high ascertainment results from 93 Trusts in the GAP programme show no increase in stillbirth rates in the 6 months since lockdown (April-September 2020) compared to the same periods over the last 2 years.

C. **What improvements could be made?**

22. There is now ample evidence that increased awareness and emphasis on fetal growth surveillance has had a substantial impact on reducing stillbirth rates. However, the same evidence has highlighted that much more can be done, by extending the benefits to all maternity units.

23. From a mother's perspective, there is currently an element of postcode lottery about the quality of care she will receive during her pregnancy. At parents' request, we list on line which Trusts have taken up the GAP programme [11]. However in reality, mothers often have little choice but to accept the care offered in their local hospital. Stronger, centralised recommendations would allow them to receive standardised, best evidence based treatment wherever they access the NHS.

24. Maternity services need to be better supported in implementing a high standard of care. In the area of fetal growth and wellbeing, as in ante- and postnatal care generally, there are special challenges in delivering safe services to ethnic minorities and socially deprived communities.

25. Clinical support ought to include local leads to co-ordinate training in fetal growth surveillance, protocols and audit. An injection of funding for designated leads/co-ordinators by NHS North England (SaBiNE – Saving Babies in North England) had a substantial impact on performance, including antenatal SGA detection rates, which also translated in a significant reduction in stillbirth rates. [18]

26. Support for ultrasound training and resources is also essential to fulfil demanding protocols for antenatal assessment by scan and Doppler flow velocimetry. The Saving babies Lives Care Bundle v2 (2019) [19] introduced Doppler investigation requirements for which many services were not ready, and in many areas are still struggling to fulfil. There is also a continuing shortage of ultrasound scan resources which are required for serial assessment of fetal growth according to RCOG, SBL-CBv2 and GAP guidelines. Mothers with a high risk pregnancy who do not receive serial third trimester scans have a 2 fold increased risk of stillbirth [20].

27. Currently the Saving Babies' Lives Care Bundle v2 [19] Fetal Growth element requires a composite metric (babies <3rd centile size not delivered by 37+6 weeks) as a CNST requirement, but this is an imprecise indicator in a multi-ethnic population with varying norms for fetal size [21] length of pregnancy [22]. Performance can be monitored better through a set of specific process and outcome indicators like referral and SGA detection rates as well as false positive rates, which we provide routinely to GAP units. Such parameters help clinicians to identify local hurdles. There ought also be a requirement to audit near-misses (SGA cases not antenatally detected), to try to understand reasons why the system might fail to identify fetuses at risk due to growth restriction.

28. There is a need to standardise assessment of birthweight across disciplines: RCOG guidelines [15] recommend customised assessment, and most pregnancies in the NHS are assessed by this standard. At the same time, most neonatologists still use the one-size-fits-all UK/WHO standard from 1990 [23]. This means that the mother may hear conflicting assessments of her newborn, as her care is passed from maternity to neonatal teams. Apart from confusion, this can have

implications for patient safety [24], for example when missing warning signs for sudden unexplained deaths in infancy (SUDIs) [25].

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Oct 2020