5th April 2017

Mr Edward Morris FRCOG
Vice President, Clinical Quality,
Royal College of Obstetricians and Gynaecologists

Mr Tim Overton FRCOG
President, British Maternal and Fetal Medicine Society

Open Letter: K2 Response to RCOG/BMFMS Circular 31st March 2017

Dear Mr Morris and Mr Overton,

We welcome the RCOG/BMFMS lead on encouraging debate around the findings and interpretation of the recently published INFANT Study. In the spirit of debate we should like to respond to the two areas of concern raised in the RCOG/BMFMS circular.

1. **'It is not appropriate to use these data [BirthPlace poor outcome incidences and INFANT Study incidences] to draw conclusions about the efficacy of the INFANT-Guardian technology'.**

The INFANT Study found no difference between the two arms of the trial tested, INFANT+Guardian versus Guardian alone, because the study design was flawed. The nature of the flaws were set out in the Lancet publication, (http://dx.doi.org/10.1016/S0140-6736(17)30714-6) The trial design was known to be flawed by all involved at the time of making the application to the NIHR in 2006. Members of the INFANT Clinical Investigators Group, INFANT Clinical Collaborators and NIHR referees made the issues clear at the time. The contemporaneous correspondence related to this matter is published http://www.k2ms.com/library.aspx. Despite these issues, this flawed trial design went forward un-amended.

K2 believes that comparing the incidence of poorest perinatal outcomes found in the INFANT Study against those found in UK Obstetric Units during the BirthPlace Study ***is*** a valid comparison with due acknowledgement that BirthPlace and INFANT considered different risk populations; BirthPlace low risk pregnancies, INFANT high risk pregnancies.

BirthPlace Eligibility: Women with a single pregnancy who had completed 37weeks gestation, were assessed as low risk around the time of labour, were tended by a midwife at least once, excluding congenital abnormalities. There were 36 UK Obstetric units involved and some 19,551 women recruited to this hospital place of birth. See page 36 of the

Birthplace clinical report.
http://www.k2ms.com/documents/infant/Birthplace_FULL_Clinical_report_2011.pdf

BirthPlace was intended to capture population statistics for low risk women according to their intended place of birth. It was intended that Birthplace be used to make comparisons between different environments of care during labour.

INFANT Eligibility: Women with a single or twin pregnancy who had completed at least 35weeks gestation, were assessed as high risk sufficient to require continuous fetal monitoring prior to or during labour, excluding congenital anomaly. There were 24 hospitals involved and some 47,000 women recruited. The full eligibility criteria can be found in the INFANT protocol,
http://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-015-0780-0

Emergency admissions that bypassed labour ward were not eligible for either study. Neither study recruited elective Caesarean Sections.

Incidence of poorest perinatal outcomes in BirthPlace.
For a low risk woman, giving birth in a UK obstetric unit, the risk of Stillbirth was 2.6 per 10,000 births and of moderate / severe brain damage, 2.0 per 1,000 births. The overall incidence of poorest perinatal outcome (IP Stillbirth + Neonatal Death + moderate/severe Brain Damage) was 2.57 per 1,000 births.

Incidence of poorest perinatal outcomes in INFANT Study.
INFANT recruited 47,000 births and represents the population of high risk women giving birth in UK obstetric units that used INFANT-Guardian technology. The hospitals that took part in the INFANT Study represented the entire installed base of INFANT-Guardian in the UK.

For a high risk woman, giving birth in a UK Obstetric unit that used INFANT-Guardian, the risk of Stillbirth was 0.6 per 10,000 births and of moderate / severe brain damage the incidence was 0.78 per 1,000 births. The overall incidence of poorest perinatal outcome (IP Stillbirth + Neonatal Death + moderate/severe Brain Damage) was 1.1 per 1,000 births.

This comparison is summarised in the following table.

	INFANT-Guardian® Hospitals' Incidence INFANT Study	**Other UK Obstetric** Hospitals' Incidence BirthPlace
Intrapartum Stillbirths	**0.6** per 10,000 births	**2.6** per 10,000 births
Moderate or Severe Brain Damage	**0.78** per 1000 births	**2.0** per 1,000 births
Poorest Perinatal Outcomes *(Stillbirths + Neonatal Deaths + Brain Damage)*	**1.1** per 1,000 births	**2.57** per 1000 births

Conclusion

Some are taking the null finding of the INFANT Study to question the physiological basis of fetal heart rate to assess fetal wellbeing during labour. Such a conclusion would obviously apply equally to CTGs and intermittent auscultation as both observe the same physiology. Such an interpretation would set care during labour back decades, if not a century in our view.

But such a conclusion is to ignore the forseen flaws of the study design and the very low incidences of poorest perinatal outcomes observed in 47,000 births. There was no difference between the arms of the INFANT Study, not because both arms offered poor care or typical care, but because both arms offered low risks of human errors leading to poorest perinatal outcomes.

K2 is promoting a positive message that with technology to facilitate communication and senior clinical staff oversight (Guardian) and technology to monitor fetal heart rate continuously, to alert remotely and help improve clinical skills at the point of care (INFANT), that human errors that so blight life chances of a significant few can be reduced.

There was no case of hypoxic outcome for which INFANT failed to raise appropriate concern in a timely manner. INFANT can be seen as a logical progression of the rationale behind the RCOG/NICE guidelines for CTG interpretation, bringing a standard model of interpretation right to the point of care. The difference being that INFANT works in real time, is consistently applied and has undergone unprecedented evaluation. All parties agree that INFANT offers no negative effects.

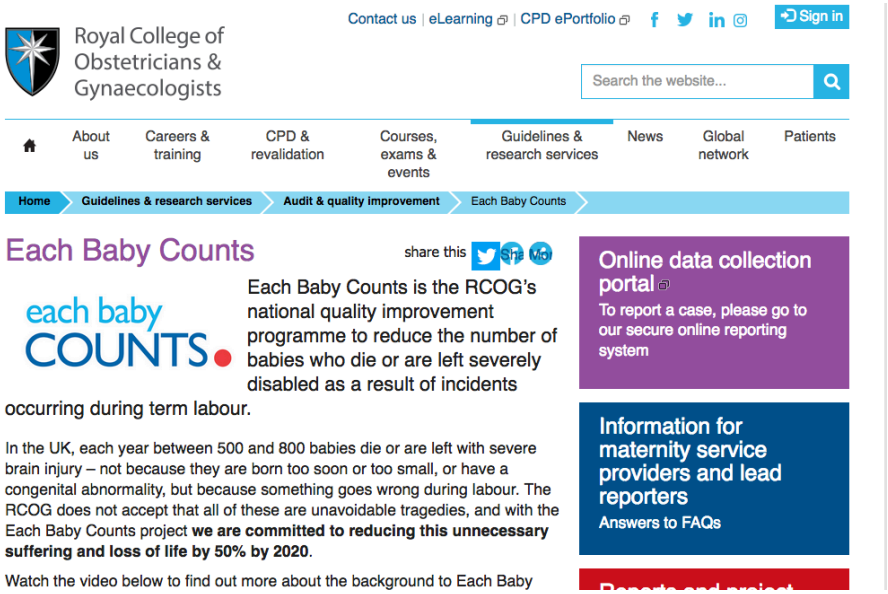
A full elaboration of K2's rationale and intended approach can be found in our publication, 'Improving Birth Outcomes, A series in four volumes' available to download or view from www.k2ms.com/infant

K2 would very much like to work with the RCOG and BMFMS to bring about improvements in birth outcomes. Goals that both our organisations are committed to attempt to achieve. We would be happy to meet at any time with RCOG/BMFMS to explore how best to achieve this common aim.

The second point raised in the RCOG/BMFMS response was,

2. **'We are also concerned by the erroneous claim in the press release that the RCOG "suggest that some 800 babies per year are unnecessarily stillborn or permanently brain damaged during labour". '**

K2 suggest that the extract from the RCOG website [below] supports our statement.



Yours sincerely,

Dr Robert Keith MEng CEng FIET PhD
Director General