



PRESS RELEASE

K2 Medical Systems, Plymouth, UK

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Following publication in the Lancet⁶, K2 Medical Systems (Plymouth, UK) release INFANT-Guardian[®] technology that has been found in the largest maternity trial ever funded by the NHS, to help **reduce stillbirths during childbirth by a factor of FOUR** and **reduce the numbers of babies born brain damaged by HALF** compared to UK obstetric units who do not have the K2 technology.

What are the problems in fetal heart rate monitoring ?

There are TWO main problems in the care of women during labour in UK hospitals that can lead to poor birth outcomes,

Problem 1: Care of a woman in labour is usually delegated to a single clinician, usually a midwife, who becomes responsible for interpreting the wellbeing of the mother and their baby. The appropriate care a woman needs depends on this clinician reaching a correct and timely diagnosis from which senior staff are called if deemed necessary. This system of care is flawed. There is an over-reliance on individual clinicians that set up single points of failure. If the clinician is out of the room, as they are at least 27% of the time⁸, or is busy looking after two women at the same time or fails to interpret events correctly, perhaps because they are newly qualified or junior, then problems are not identified and appropriate staff are not informed.

Problem 2: The interpretation of fetal heart rate monitoring during labour is difficult and clinicians make errors of interpretation that directly contribute to babies being stillborn or permanently brain damaged during labour. This problem has been recognised for 30 years but unsolved, until now. Until INFANT[®].

Consequences: The Royal College of Obstetricians and Gynaecologists suggest that some 800 babies per year are unnecessarily stillborn or permanently brain damaged during labour⁵. Medical Negligence claims for birth related poor outcomes cost the NHS over £500million per annum^{1,3}. Some £700 is paid into a central risk pool to compensate malpractice by hospitals for every single baby born in the UK. The former chair of the Finance Committee, Margaret Hodge, described this as, 'scandalous' (full quote below). The National Audit Office assessed that costs of obstetric negligence amount to 20% of the entire NHS maternity budget².

The UK Government has mandated the NHS to improve. It has mandated the NHS to reduce these poorest perinatal outcomes by half by 2030 with a measurable reduction

by 2020. But given that all obvious approaches so far have been tried, and failed, including enhanced training, NICE Guidelines and maternity national standards with OFSTED style onsite aggressive audit, K2 technology is the only realistic solution.

Full details including a video and infographic presentation can be found at www.k2ms.com/INFANT

K2MS Guardian™ addresses Problem 1. What is Guardian™ ?

Guardian™ is a K2 technology designed to address Problem 1 above. Guardian™ captures all information and care at the bedside within the delivery room and projects this information out of the birth room and around the hospital. Guardian™ is the communicator. Guardian™ ensures that senior staff at central locations, in their offices or on call in their homes can have oversight of all care taking place on labour ward, for low risk and high risk women. Senior staff no longer have to wait for junior staff to inform them of a problem. They have continuous oversight and can become involved whenever they deem necessary. Guardian™ is K2's response to Problem 1 which identifies an over-reliance on junior staff. Guardian™ ensures that there is greater vigilance and facilitates team-working and communication.

Full details including an infographic presentation can be found at www.k2ms.com/INFANT

K2MS INFANT® addresses Problem 2: What is INFANT® ?

INFANT® is our response to Problem 2. INFANT® is computer interpretation of fetal heart rate monitoring during labour. It has taken almost 30 years to develop and evaluate. INFANT® effectively puts a proven expert in fetal monitoring at every bedside 24 hours a day to interpret every minute of fetal heart rate recording obtained. INFANT® diagnoses fetal condition to the standard of an expert and raises appropriate concern, at the bedside and to senior staff throughout the hospital and offsite. If ignored, INFANT® has an alarm tone and then resorts to a human voice to summon care if ignored further. INFANT® has been assessed in the largest maternity technology evaluation ever undertaken in the UK that involved 47,000 births across 24 hospitals. INFANT is regulatory approved for immediate release.

Full details including a video and infographic presentation can be found at www.k2ms.com/INFANT

What is the INFANT® Study and what did it find ?

The INFANT® Study was an NHS funded trial that recruited 47,000 births. The results show that the model of care practised in the INFANT® Study led to very low incidences of poorest perinatal outcomes. The incidence of stillbirth observed in the INFANT® Study (0.6 per 10 000 deliveries) was 4 times less than that found for low risk women in UK Obstetric units (2.6 per 10 000),⁷ the incidence of brain damage was less than half (0.78 per 1000 vs 2.0 per 1000)⁷ and the combined incidence of stillbirth, neonatal death, and moderate or severe brain damage in the INFANT® Study (1.1 per 1000) was less than half that found in UK Obstetric Units (2.57 per 1000)⁷.

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Reaction

Dr Robert Keith, Director of K2 Medical Systems and inventor of the technologies said, 'This is an immensely proud moment for us all at K2 Medical Systems. We have been working on developing and evaluating these technologies for almost 30 years now. A huge effort sustained over a long period of time with the aim of reducing unnecessary harm to babies during birth. We are delighted to be finally announcing the release of our technology into clinical practice.'

K2 Medical Systems will be contacting Government, Ministers, NHS Litigation Authority, NHS England and Scotland and interested parties to fully brief them on these developments. Our hope is that INFANT-Guardian® will become a national standard of care.

Margaret Hodge, the former Chair of the Public Accounts Committee, said at the time of the publication of the NAO report²: “I find it absolutely scandalous that one fifth of all funding for maternity services, equivalent to around £700 per birth, is spent on clinical negligence cover. The current system is not working as it should. The Department needs to buck up and take responsibility for this. It needs to review its monitoring and reporting process to ensure that all relevant bodies can work effectively together to deliver maternity services that are value for money and fit for purpose.”, Nov 2013

Contact and Further information

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About K2 Medical Systems

K2 Medical Systems is a multi-award winning innovation and technology company dedicated to improving maternity care. In 1989, we started life as The Plymouth Perinatal Research Group a Medical Research Council (MRC) grant funded research team based within a busy maternity department in Plymouth. In 1999, K2 Medical Systems was formed to further develop our research and transfer our technologies into healthcare, where they could do good. K2 is now a global organisation with offices in the UK, Australia and USA.

References

- [1] NHS Litigation Authority Annual Report and Accounts 2014/15
- [2] National Audit Office Report. Maternity Services in England. 8th November 2013
- [3] NHS Litigation Authority Annual Report and Accounts 2015/16
- [4] The Government’s mandate to NHS England for 2016-17. January 2016 Objective 2
- [5] Each Baby Counts Royal College of Obstetricians and Gynaecologists. Key Messages from 2015. Page 5
- [6] Computerised interpretation of the fetal heart rate during labour (INFANT): a randomised controlled trial. The INFANT Collaborative Group. www.thelancet.com from March 22nd 2017
- [7] Hollowell J, Puddicombe D, Rowe R, Linsell L, Hardy P, Stewart, M, et al. The Birthplace national prospective cohort study: perinatal and maternal outcomes by planned place of birth. Birthplace in England research programme. Final report part 4. NIHR Service Delivery and Organisation programme; 2011. Pages 69-79 and Tables 22, 23 and 26
- [8] ‘An investigation of labour ward care to inform the design of a computerised decision support system for the management of childbirth Dr Maureen Harris. PhD Plymouth Perinatal Research Group, University of Plymouth 2002 ETHOS ID: uk.bl.ethos.268662