The INFANT Study

A multi-centre Randomised Controlled Trial (RCT) of an intelligent system to support decision making in the management of labour using the CTG
Why the INFANT Study

- INFANT stands for INtelligent Fetal Assessment Monitoring

- The INFANT Study is the 2nd largest study funded by the National Institute for Health Research Health Technology assessment Programme (NIHR HTA) – Department Of Health

- The question was asked by the HTA in 2006 if decision support systems could improve labour outcomes.
Main aim of electronic fetal monitoring (EFM) is:

- To detect fetal compromise during labour
- Prevent consequences of intrapartum asphyxia by prompt delivery
- Introduced without RCT

Consequences of perinatal asphyxia include:

- Stillbirth
- Encephalopathy - moderate/severe ~2/1000 births
- Severe encephalopathy associated with ↑risk of death or neurodevelopmental abnormalities
- ~25% of those with moderate enceph will develop CP
- Perinatal asphyxia may account for up to 30% of CP cases
- The risk of intrapartum death is virtually unchanged since 2000.

(Perinatal mortality, CEMACH 2008)
NHSLA Claims 2000-2010

- 5,087 maternity claims
- £3.1 billion.
- 5.5 million birth
- Less than 0.1% birth had become subject of claim.
- CTG misinterpretation leading to CP, accounted for 70% of the total value of all the maternity claims.
Major & costly human errors in the interpretation of fetal heart tracing are:

- Relatively common
- Inexperienced staff,
- Night shift working patterns
- Staff shortages
- Compulsory training for all staff in interpretation of fetal heart-rate pattern…. Effective?

Alternative intervention is a computer-based expert system to help support the clinician
K2 Medical Systems have developed decision-support software called Infant®:

• For use with Guardian® system to identify abnormalities

• The RCT provides a window of opportunity for rigorous testing of software:
  - if RCT confirms hypothesised benefits - could have rapid rollout. Women and babies would benefit immediately. ↓ Intrapartum stillbirths and encephalopathy
  - if RCT identifies problems – these must be addressed before widespread or any adoption of software
Potential benefits of decision-support:

• Improved **neonatal outcomes**
  e.g. intrapartum stillbirth & encephalopathy

• Decreased **intervention in labour** – fewer
  CS for presumed fetal distress

• Improved “**quality of care**” making proof of
  negligence during intrapartum care more
difficult to confirm
INFANT Study objectives

1. To determine whether the decision-support system can improve the management of labour using the CTG in women judged to require continuous EFM.

2. To determine whether the use of the system is cost-effective.
Study setting

Design: Randomised Controlled Trial

Setting: Hospital labour wards in UK and Ireland

Eligibility: All women admitted to labour ward:
- At ≥ 35 weeks gestation
- Aged 16 years or older
- Singleton or Twins
- Able to understand English
- Able to give consent
- With no gross fetal abnormality
Study Arms

**Intervention:** CTG monitoring + decision support.

**Arm:** Clinicians will be asked to acknowledge and consider the output presented by the decision-support software.

**Control:** CTG monitoring with no decision support.

**Arm:** Each centre will adhere to their current labour ward guidelines for CTG monitoring and interpretation; all guidelines include the use of selective fetal blood sampling.
Antenatal information supplied to all women

All labour ward admissions ≥ 35 weeks gestation, no known fetal abnormality including arrhythmia, singleton or twins, ≥ 16 years old and able to consent. Women are asked for their consent to enter the study if continuous EFM is initiated at any point in their labour.

Intermittent auscultation

Decision made to initiate continuous EFM

Continuous electronic fetal monitoring

Randomisation via Guardian

Control Arm
CTG monitoring with no decision support

Intervention Arm
CTG monitoring with decision support
Randomisation (1)

• Each Guardian® labour ward system will randomly assign women to “no decision-support” or “decision-support” once the woman’s consent has been registered into the Guardian® system and continuous CTG monitoring has been initiated.

• Prior to this the midwife or doctor must have confirmed that continuous CTG monitoring is required.
Randomisation (2)

- 46,000 women need to be randomised into the study
- 23,000 women will be randomised into the control arm
- 23,000 women will be randomised into the intervention arm

The system will prompt staff looking after eligible women in regards to asking about the study.
When it has been entered into Guardian® that consent has been given and CTG monitoring is to take place, randomisation will occur.
There is no extra telephoning or internet access needed.
Difference between the arms

• Women randomised to the control arm – their screen will look like Guardian® currently does.

• Women randomised to the intervention arm – their screen will look slightly different and a new ladder of concern will appear on the Guardian® screen.

• (Note women cannot have the Infant® software used on their labour if they have not consented to take part in the study.)
Infant® Ladder of Concern

This ladder of concern is positioned next to the patient details and will indicate a colour coded system identifying any concern that it may have and highlight what the concern is.
Infant® ladder of concern levels

**GREEN** – Indicates that there are no concerns with the CTG (level 4)

**BLUE** – Indicates that there are minor concerns with the CTG (level 3)

**YELLOW** – Indicates that there are serious concerns with the CTG (level 2)

**RED** – Indicates that there are urgent concerns with the CTG (level 1)
Infant® Green Ladder of Concern
Infant® Red Ladder of Concern

[Image of a screen showing a graph with annotations for severe decelerations and contractions, along with timestamps and action buttons for acknowledge and admin.]
Primary outcomes

“Poor neonatal outcome”:  
- Deaths:  
  - intrapartum stillbirth  
  - neonatal  
- Significant morbidity:  
  - Seizures & other admission to NICU within 48 hrs of birth for ≥ 48 hrs with evidence of encephalopathy, feeding difficulties or respiratory illness

Developmental questionnaire at age 2 years
Secondary outcomes – infant

Infant outcomes:

• Cord-artery pH < 7.05 with base ≥ 12 mmol/l
  – threshold above which risks of neurological damage increase

• “Adverse outcome”
  – Trial primary outcome plus
cord-artery pH < 7.05 with base ≥ 12 mmol/l judged to have had suboptimal care

• Apgar < 4 at 1 minute

• Fetal blood sample values
Secondary outcomes – mother

Maternal outcomes:

- Caesarean section
- Length of labour (1st stage, 2nd stage, total)
- Any operative intervention (CS, forceps, ventouse) for:
  - Fetal distress
  - Failure to progress
- Episiotomy
Data collection – long term

Long term outcomes (age 2 years):
• Postal questionnaire completed by family - 2 parts:
  – PARCA assesses neurodevelopment – validated in a trial setting
  – Focuses on general health
  – 7,000 participants will be followed up

Economic evaluation
• Prospective data on resource utilisation using:
  – Decision-support system
  – Hospital-patient administration & maternity information systems
  – Patient notes
  – Economic questionnaire of 700 participants
Recruitment

Assumptions

• 60% of women will require continuous EFM (NICE guideline; 80% of primigravidae continuous EFM in Liverpool)

• 60% recruitment rate of eligible women

• 36 month recruitment period now extended

• Recruit about 354 women per week internationally (18,408 pa)
  – i.e. delivery population of 983 per week (51,000 pa)
Lead Midwife for K2
Phoebe Turnbull
INFANT TEAM
Homerton University Hospital
Natasha McGhee and Silvia Segovia
Thank you to all the midwives, doctors and patients of HUH.

Any Questions
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