Clinician Review and Recommendation re. the implementation of K2 INFANT as part of Business Plan:

'Purchase and implementation of a Central Foetal Monitoring System for Singleton Hospital Obstetric Unit'

Summary

We are passionate about high quality, maternity care provision and developing our service to meet the needs of women and their families within Swansea Bay. As part of this we are looking forward to enhancing the care we provide in purchasing a central monitoring system that provides us with a paperless, digital solution. However, in relation to the INFANT software (free of charge with the purchase of K2 Guardian) for the reasons outlined below, we recommend:

1) Not implementing the additional K2 INFANT into Maternity Services in Swansea Bay

K2 INFANT is a small, additional element of the whole system we have purchased, and has not come at a cost. We have concerns over its' use in practice (as outlined below) and our preferred option would be to not have it implement within clinical practice.

2) If our preferred option is not a possibility, we would then recommend a staged approach to the introduction of K2 INFANT

This is to ensure adequate time for training within an already tight schedule, which we should not delay further. We want the transition to be as supportive for staff as possible, minimise clinical incidents, allow time for policies to be written and agreed upon in relation to INFANT and reduce any negative impact on women's experience. Allowing time for staff to get used to central monitoring before introducing INFANT would aid in this process.

Discovering the mandatory introduction of INFANT has caused significant concern among clinicians, who were previously reassured **this would not be mandatory**. Although it is only a small feature of the overall project, we recommend this is paused whilst we consider the potentially far-reaching implications of introducing INFANT.

- The findings from the INFANT Trial concluded that INFANT does not improve outcomes for women & babies, has not been shown to support midwives or doctors in their decision-making/escalation and did miss CTG abnormalities. This finding is supported by 3 other RCTs in the UK.
  NB: There is a relatively small experimental study in Australia showing there may be improved outcomes, however it was limited due to use of composite primary outcomes & unexplainable data change (Wilson et al., 2021).

- As the only Health Board in Wales proposing to have INFANT, it will have implications for our alignment with All Wales efforts to standardise fetal monitoring for trainees and our governance processes

- There will be 2 tiers of assessment ongoing on the CTG (INFANT assessment and reaction & CTG Classification sticker assessment (Welsh Risk Pool mandated). This will increase clinician workload and has the potential of creating confusion amongst clinicians and governance processes.

- As it is unexplored, we cannot predict the unintended consequences the introduction of INFANT will have on our service. The evidence available has not explored the impact such a system has on clinicians in practice. There exists ethnographic studies that have described the impact on clinical behaviours, workload, women's experience, remote 'reviews', and midwives being absent from the room, which will require significant implementation effort to mitigate against for central monitoring to be implemented well. The addition of INFANT on top of this will further complicate this process.

Please note: The Independent Maternity Review, 'Ockenden Report' (2022) has boldly stated that all units must implement a central monitoring system. A central monitoring system is not to be confused with INFANT. The Ockenden report does not encourage the use of a decision-support software such as INFANT.

Detailed Clinician Review

What is K2 INFANT software?

It is a decision-support software that was developed to run on the K2 Guardian system alongside central monitoring. INFANT makes an assessment of the overall fetal heart rate pattern and then produces a colour coded alarm to alert clinicians. It does not take into account the whole clinical picture and does not recommend a course of action. INFANT works in addition to K2 Guardian, which, when used to full capacity can provide full electronic capture of patient information during childbirth.

INFANT software does not improve outcomes for women and babies

"The INFANT trial set out to assess whether decision support would improve the recognition of abnormal CTGs and thereby improve outcomes. We have shown clearly that the system tested does not achieve this." (Brocklehurst et al., 2017).

Extract from SBUHB Business Case for Central Fetal Monitoring:

"K2 has INFANT algorithms that have been proved to interpret the CTG more consistently and to a higher level than experts. In the trial "INFANT" was proven to never miss a CTG abnormality. The clinical outcome from the trial showed that the rate of the poorest outcomes were lower than that identified in the Birthplace study (2011). While the INFANT algorithm will detect CTG abnormality the interpretation and escalation of the findings are necessary by the clinicians taking into consideration the whole clinical picture. The INFANT algorithm is additionality which will support the midwife providing care in the clinical decision making and escalation."

The authors of the INFANT Trial concluded that INFANT does not improve clinical outcomes for women and babies (Brocklehurst et al., 2017). The INFANT randomised control trial (Brocklehurst et al., 2017) set out to assess whether decision support (i.e. INFANT) would improve the recognition of abnormal CTGs and thereby improve outcomes.

"We noted no difference in the incidence of poor neonatal outcome between the groups—172 (0·7%) babies in the decision-support group compared with 171 (0·7%) babies in the no-decision-support group (adjusted risk ratio 1·01, 95% CI 0·82–1·25). At 2 years, no significant differences were noted in terms of developmental assessment. (Brocklehurst et al., 2017).

The strengths of the trial include 47,062 participants within UK NHS systems. There is a direct comparison in the use of INFANT/no INFANT on top of the use of Guardian (which is relevant to our context). However, K2 Guardian was introduced at the same time and has been criticised for influencing the findings, as well as operating a different care model as compared with the rest of the UK, who do not use Guardian. As a co-located un-blinded RCT this meant significant design flaw as staff looked after the women in both arms simultaneously, allowing for cross-effect.

These concerns were raised by the study design team and Robert Keith. As a result of his direct involvement as Director General of K2 and as author of The Lancet paper he resigned as in 2016 based on the flawed nature of this study. See excerpt below:

"I am the co-inventor of INFANT and have been responsible for its development from 1989 to date. I am co-founder and Director General of K2 Medical Systems who own the INFANT technology and have been involved in the INFANT Study from 2006. I was a member of the authorship and member of the Clinical Investigator's Group. I was responsible for the operational aspects of the Study associated with INFANT technology. I resigned as author of the Lancet paper on Nov 1, 2016." (Keith, 2016).

It is not the INFANT trial alone which has failed to demonstrate improved outcomes using a computer analysis software package in labour. An RCT of 5 hospitals within the UK of 7320 participants found that computer analysis of fetal monitoring signals with real-time alerts did not significantly reduce the rate of metabolic acidosis or obstetric intervention (Nunes et al., 2017). In addition, Campanile et al. (2020) conducted a systematic review and meta-analysis of the RCTs available (n=3) totalling 54,492 participants, and concluded no significant reduction of injury or obstetric intervention.

In summary, K2 INFANT software has not been shown to:
- Interpret CTGs to a higher level than 'experts'
- Improve management of the CTG, despite more 'consistently' alarming
- Support clinicians (midwives and doctors) in their decision-making or escalation

Is there any harm in introducing it?

We write this in a context of national and international recommendations for the use of the CTG in high risk labours. The CTG is a screening tool that has low specificity and high sensitivity, increasing likelihood of unnecessary caesarean birth and intervention, with no offsetting benefit for mother or baby. This makes it a challenge for use in clinical practice. To date, research evidence has failed to demonstrate perinatal benefits from CTG alone, even for women with babies at risk of poor perinatal outcomes (Small, SIdebotham, Fenwock & Gamble, 2020). Efforts to supplement the CTG including ST segment analysis, fetal oximetry, central monitoring systems, and fetal blood sampling have also failed to

demonstrate improvement in perinatal mortality.
Therefore, while the endeavour to improve CTG monitoring through another system such as INFANT is welcomed, in the absence of robust, demonstrable benefit to women and babies we do not accept its' introduction into practice, without any proven benefits.

While the trials have not found an increase in harm or poor outcomes with the use of INFANT/decision-support technology in terms of perinatal morbidity and mortality, these studies did not consider women's or clinician's experience of the introduction of this system into their clinical area. Available to us are small, ethnographic studies conducted around the implementation of a central monitoring system and these have highlighted unintended consequences, such as,

- Changes in clinical behaviours, i.e. midwives being absent from the room (the screens as a 'babysitter')
- Collegial conduct
- Respectful communication
- Threat to privacy and dignity of the woman
- Effects on the birth space of the woman and uninvited clinicians coming into the room unnecessarily, e.g. when women using bedpan and loss of contact on a CTG prompting entry
- Clinical reviews being performed remotely, based on the CTG alone, without the inclusion of the mother or the full clinical picture
- Midwives assuming someone else is watching the CTG, however this may not be the case and action therefore not taken

The Introduction of INFANT, in addition to Guardian, will increase midwives' and Doctors' workload, there will be significant training required, including new skills in using a system that has no ability to improve outcomes and in the meantime, we could expect the challenges listed above to be magnified without any benefit. There is also concern amongst clinicians that a decision-support software may have the unintended consequence of midwives and doctors failing to think and analyse the CTG based on their own knowledge and experience. This may potentially create a situation where understanding and interpretation of the CTG is eroded. In addition to this, unfortunately we cannot include women's experience within this discussion as this has not been evaluated.

Acceptance of the introduction of K2 INFANT just because it has not been shown to worsen outcomes stands in opposition to the ethical principle of nonmaleficence, where, in this case, the benefit does not outweigh the potential harm.

Our conclusion in relation to the use of INFANT within our context

We do not recommend the introduction of the K2 INFANT system into Swansea Bay University Health Board, based on the available research and evidence base, as outlined above. There are no other units within Wales who have accepted this alongside their central monitoring systems. There are no national reports recommending this technology to act as drivers for implementation.

The Project Team Clinicians

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