ST analysis plus CTG compared to CTG alone for intrapartum fetal monitoring (the START randomised controlled trial): A cost minimisation study.

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Abstract

Objective: To undertake a cost minimisation study of ST analysis (STan) plus cardiotocograpy (CTG) compared to CTG alone. **Design:** Cost-minimisation analysis alongside a randomised controlled trial [(1)](#ref-0001). **Setting:** A tertiary level maternity centre in Adelaide, South Australia. **Population:** Women in labour [?]36 weeks gestation, with a clinical indication for continuous electronic fetal monitoring. **Methods:** We utlilised a health service perspective covering randomisation to final maternal and neonatal discharge, including readmissions. Primary analysis was intention to treat, with secondary per protocol analysis. *Post hoc* analyses were conducted by sub-groups and after exclusion of outliers. **Main outcome measure:** Average cost per mother/baby dyad. **Results:** Costs were calculated for 957/968 patients (98.9%) using hospital financial data. There was no statistically significant evidence of difference between the two study arms but lower costs observed in the STan arm. Average cost per mother/baby dyad was AUD12,768 for Stan+CTG, compared with AUD15,027 for CTG alone. Lower costs were mainly due to lower neonatal costs, particularly for critical care. Maternal labour cost was nearly identical in the two arms. The difference was still shown, although with reduced magnitude, when outliers were removed and increased with a per protocol analysis. **Conclusion:** While not statistically significant, reduced costs were observed in the CTG+STan arm (average reduction per mother / baby dyad = AUD2,259).

Research Paper

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Keywords: Cost-minimisation analysis, STAN, ST analysis, CTG, cardiotocography

Introduction

In contrast to the UK's NHS Resolution organisation, Australian health care lacks an "arms length" institution to manage medico legal issues. NHS Resolution's 2021-2022 annual report (2) revealed that compensating for harm caused by NHS maternity services costs almost three times what the health service spends on maternity care (GBP 8.2 billion, compare to GBP 3 billion spent on care). Cumulative maternity services' liability has reached GBP 41.5 billion. (GBP 38.8 billion relating to cerebral palsy).

Continuous Electronic Fetal Monitoring (CEFM) (3) aims to identify intrapartum hypoxic stress to avoid HIE and intrapartum-related perinatal deaths. Meta-analysis of RCTS studying both high and low risk women (4) shows show reduced neonatal seizures, but without significant reduction in cerebral palsy. It has been argued that such meta-analyses still lack the power to detect significant reductions in severe adverse fetal outcomes, given the rarity of such outcomes among all risk women (5). It is evident that the devastating

impact of cerebral palsy, frequently associated with inadequate utilisation of fetal monitoring or substandard staff education, has created the unsustainable situation described above (6) .

ST analysis (STan) is an adjunct to CTG, introduced at the study institution as a standard of care in 2015, aiming to better identifying hypoxic stress, thus to keep babies safer. It was also anticipated in our RCT that STan as an adjunct to CTG (CTG+STan) would reduce the proportion of emergency caesarean sections (EmCS) from false positive diagnoses of fetal distress (7), relative to CTG alone. However, clinical results of our RCT (1) did not demonstrate significant evidence of a reduction in the proportion of EmCS in women requiring CEFM in labour, but we did show a smaller proportion of poor neonatal outcomes in the CTG+STan arm (relative to CTG alone), although the study was underpowered to detect a decrease in metabolic acidosis or other adverse neonatal outcomes.

With cost-effectiveness analysis of maternity interventions being further recognised for the allocation of health resources and strategies of clinical care, the lack of a published economic evaluation of CEFM may be a barrier in the implementation and provision of appropriate intrapartum fetal surveillance. The objective of this study was to identify the cost minimising approach, by quantifying costs in the context of clinical equivalence in each arm of the randomised controlled trial. Thus, we have performed a cost minimisation study, as a specific type of cost effectiveness study (8).

Methods

Clinical study

A single-centre, RCT was conducted from January 2017 to July 2021) at the largest tertiary care centre in South Australia (Women's and Children's Hospital , North Adelaide) (Australian Clinical Trial register number ACTRN12615001308583; Womens and Childrens Health Network Human Research Ethics Committee approval (HREC/14/WCHN/145). Eligibility for the trial included: being aged 18 years or older with a singleton pregnancy; a fetus in cephalic presentation; a gestational age >36weeks and an indication for CEFM based on RANZCOG guidelines(9). Women were randomly allocated (1:1 ratio with stratification for parity) to monitoring either by CTG+STan or CTG alone(. The primary hypothesis was that the proportion of EmCS for women on CTG+STan is not equal to that for women on CTG monitoring alone. Our secondary hypotheses included that CTG+STan monitoring is cost-effective compared to CTG alone (8).

For women assigned to CTG+STan, a fetal scalp electrode (FSE) was applied to the fetal head and connected to a STAN® fetal heart monitor (STAN, Neoventa Medical, Mölndal, Sweden)(10), which allowed both conventional CTG interpretation and ST analysis of the fetal ECG. Further clinical management was made using the STan clinical guidelines [STAN2007 CTG classification system] (11), in addition to CTG classification and interpretation according to the RANZCOG clinical guidelines (9). In women assigned to CTG alone, either an external doppler transducer was utilised, or a FSE was applied to the fetal head and a conventional fetal heart rate monitor (Philips or Neoventa) was used. The CTG was classified and interpreted according to the RANZCOG clinical guidelines (9) Clinical decisions were based on overall clinical assessment combined with STan and/or CTG interpretation, as described in further detail in the study protocol (8).

Cost measurement and valuation of resource use

The primary outcome of EmCS occurred in 107/482 (22.2%) of the CTG+STan arm and in 107/485 (22.1%) in the CTG alone arm, adjusted relative risk (RR) 1.02; 95% confidence interval (0.81 to 1.27), P=0.89 (1). In addition to observing the primary outcome, data from various clinical feeder systems were used to identify the level of care provided and the subsequent resource inputs for each patient. All inpatient costs were calculated on a full absorption basis (i.e. inclusion of direct and indirect costs) for each type of resource used. The preparation of costing data conformed to standards required for the National Hospital Cost Data Collection for the year of collection. This was done with the exception of two cases where known neonatal admission cost data were missing. After investigation, this missingness was assumed to be at random and costs were imputed based in average neonatal admission costs for that arm. All costs are expressed in

Australian dollars (AUD) for the financial year (FY) 2021. Costs from the FY2018 are inflated 8.3503%; FY2019, 6.1453%; and FY2020, 3.6229%, based on the inflation of the National Efficient Price (NEP) for health care services provided by public hospitals, as determined by the The Independent Hospital Pricing Authority (IHPA) (12).

The analysis used a health service perspective and included episode costs for all maternal and neonatal admissions and readmissions that occurred within a six week window from randomization.

Statistical analyses

The primary analysis was by intention to treat, with a secondary analysis consistent with the main paper as per-protocol. *Post hoc*analyses were conducted of maternal and neonatal cost subgroups and after exclusion of outliers. The economic perspective taken is that of the Australian public hospital system with total costs incurred by the hospital. Differences in costs between the two arms are presented with 95% confidence intervals and evidence was considered statistically significant if two-tailed P-values were < 0.05. All analyses were conducted using [Stata/MP version 17.0] (13).

Public and patient involvement

The knowledge and attitudes of the women in a pilot study of CTG+STan versus CTG alone were separately researched and reported (14) and subsequently, more detailed psychosocial research was incorporated into the study protocol (8). This more detailed work has been submitted for publication as studies on both patient satisfaction (15) and psychosocial outcomes (16) (unpublished observations).

In this paper, the core outcome sets have not been included.

Results

A total of 970 women were randomised; two women in the CTG+STan arm withdrew after randomisation, and one in this arm was mistakenly randomised before consent was obtained. Thus 967 women, 482 randomised to CTG+STan and 485 women randomised to CTG alone were included in the trial. Costs were calculated for 956 of these women (98.9%); the final 6 women in the STan arm and the final 5 women in the CTG alone arm were not included as their costing data was not available at the time of analysis. The two arms were similar in baseline characteristics with mean maternal age of 31 years, mean maternal gestation at randomisation of 39 weeks and cervical dilation at randomisation of 3 cm (Supplementary Table 1).

Hospital costs

There was no statistically significant evidence of a difference between the two study arms in the average cost per mother/ baby dyad for the initial ITT analysis. There were lower observed costs in the CTG+Stan arm; mean cost of AUD12,768, compared to the CTG alone arm AUD 15,027; difference = AUD2,260 (Table 1).

Insert table 1 about here

The two arms were also similar in terms of the type of costs per mother-baby dyad. Of note however, is the non-statistically significant reduction in critical care costs in the CTG + STan arm (AUD177, compared with AUD1,438 in the CTG alone arm) (Table 1).

Hospital admissions types and cost by admission type

The differences in average costs between study arms observed in Table 1 prompted further *post hoc* investigation of the admission episodes and costs by admission type. The two arms were similar in the mean percentage of mother/baby pairs that had any additional admissions for either mother or baby after the initial delivery admission (CTG+STan: 40%; CTG: 43.5%). Almost two-thirds of pairs in both arms had no additional admissions. The CTG+STan cohort had a nominally increased rate of maternal readmission, however it was also associated with fewer neonatal admissions, with particular relative reductions in neonates requiring two or more admissions, and admissions requiring critical care (Supplementary table 2). Critical care refers to Neonatal Intensive Care (NICU) where a multidisciplinary team cares for babies who need 1:1

continuous observation and monitoring and will often require respiratory support including oxygen therapy, CPAP, intubation, central line management and critical pharmacological support

Table 2 shows total and average hospital admission and readmission costs by the type of admission. Costs associated with delivery were similar across arms with a marginally (approximately 1%) higher cost in the CTG+STan arm and costs per maternal readmission were also higher in the CTG+STan arm (AUD5,188 vs AUD3,194), however given the overall low rate of readmissions the average difference (AUD142 vs AUD67) over the cohort as a whole was small (Table 2).

Insert table 2 about here

Conversely, the rate of neonatal admissions was lower in the CTG+STan arm, and the average neonatal admission costs for admitted babies were approximately half in the CTG+STan arm; AUD6,690 vs AUD13,294, which resulted in the equivalent of a cost saving of AUD2,444 *for every mother-baby dyad in the cohort* (Table 2). While the evidence of this difference was not statistically significant (given the large variability in costs, and the fact that the study was not powered to detect cost differences), the magnitude of the observed difference is remarkable. Most of the difference in cost appears to result from increased critical care costs for admitted neonates in the CTG alone arm. Interestingly, the seven neonates in the CTG+STan arm admitted to critical care had average total admission costs of about one third of the fourteen requiring critical care in the CTG alone arm (AUD30, 650 compared with AUD94, 805 per neonatal admission incorporating a critical care stay).

Excluding outlier(s)

There was an extreme outlier in the CTG alone arm (a neonatal admission costing over AUD700,000). *Post hoc* re-analysis with this dyad excluded found the magnitude of the difference in the two arms was reduced, however the findings still showed the same direction of cost differences in the CTG+STan arm relative to CTG alone, including a reduction in overall costs in the CTG+STan arm (Table 3). The direction remained when the four most extreme cost cases (i.e. all cases with total costs over AUD100,000; 3 CTG only cases, 1 STan case) were removed from analysis, with the CTG+STan arm total costs on average lower by $393 (95%CI -$1,442, $655, p = 0.2309) than the CTG alone arm, still driven largely by reduced neonatal costs (on average $579 lower (95%CI -$1,278, $120), p= 0.0523).

Insert table 3 about here

Per protocol analysis

When analysis was performed on the basis of treatment randomised being the same as that received (i.e. per-protocol), the difference in delivery costs reduced to just $87 more using STan, and the difference in maternal readmission rates and costs were also reduced. However, the magnitude of the cost difference associated with neonatal admissions was enlarged, such that difference in overall total costs increased to $2,824 per dyad, favouring CTG+STan. (Table 4).

Insert table 4 about here

Analysis by outcome

Analysis by both treatment arm and the primary study outcome (EmCS) also demonstrated the cost-saving associated with CTG+STan was present in both EmCS and non-EmCS cases, but with the finding more strongly represented in the mothers and babies who did not experience EmCS (Supplementary table 3).

Discussion

Main findings

The STan Australian Randomised Trial (START) is the first of its kind in an Australian setting. Previous European trials have been conducted in relatively low intervention environments (17-19), which, with less clinically contentious caesarean sections being performed, we hypothesised may have resulted in a lower

likelihood of demonstrating reduction in caesarean section. This rationale was supported by the results of our pilot study with 162 women (7) suggesting the potential for STan as an adjunct to CTG to reduce EmCS when implemented in a clinical setting of high caesarean section. Our findings here, while not significant, suggest that neonatal, but not maternal costs may be reduced with the use of CTG+STan. The study was underpowered to detect a difference in the main clinical outcome, EmCS (1), and the final sample size also proved to be insufficient to make conclusive statements about costs. Nevertheless the consistent direction of effect favouring the use of CTG+STan warrants further research.

The average (non-statistically significant) cost reduction of about 2,000 AUD per mother-baby pair was largely explained by neonatal cost reductions in the CTG+STan arm. STan monitoring is associated with less complexity of neonatal care (with less requirment for higher level neonatal care). Sizable reductions are shown for the sample overall, for re-admissions, and for the various sensitivity analyses, both per-protocol and with outlier exclusion.

This concurs with comparable European research. An analysis (20) based on Individual Patient Data Meta-analysis (IPDMA) (21) incorporated data from three European trials of STan monitoring (12,987 mother/baby dyads). There was consistent reduction in neonatal metabolic acidosis. Although the this reduction was not statistically significant, the authors argued that this was not unexpected as even meta-analysis were underpowered (requiring a over 24,000 patients before sufficient power would determine a difference in metabolic acidosis if it existed, at $\alpha = 0.05$). The results suggested that metabolic acidosis was reduced from 1100 to 900 per 100 000 newborns if a CTG+STan-based strategy was followed. and the cost effectiveness of CTG+STan depends on the association between metabolic acidosis and cerebral palsy. it was estimated that CTG+STan use could prevent one case of metabolic acidosis at a cost of 14 509 euros, and that STan becomes a cost effective strategy if $> 1.0\%$ of the patients exposed to metabolic acidosis developed cerebral palsy. The consistency of direction of effect and similarity in magnitude of the reduction in our study with regard to metabolic acidosis is comparable to published trials (absolute difference of about 7%).

These results suggest that STan may have a role to play in efforts to improve quality and safety of care. Whilst the focus of improving fetal monitoring has been directed at reducing maternal intervention, particularly caesarean section, recent developments in the UK have necessitated a renewed emphasis on neonatal safety (22). This re-positioning of policy (23) is partly motivated by concerns about costs for compensating for harm (24-26).

Neonatal costs may be a sensitive proxy for adverse neonatal outcomes. A failure to implement, correctly interpret and appropriately act in response to intrapartum fetal monitoring has been identified as an important association with excessive mortality and morbidity in recent reviews of under-performing maternity health services. The 2022 Ockenden report (26), recommended improvements in monitoring of fetal well-being, ensuring that clinicians keep abreast of developments in the field. Earlier reviews (27) of excessive neonatal mortality in the Morecombe Bay Report made similar recommendations, (27), as did a 2022 report by the same author concernimg the East Kent Maternity services (24).

Reviews of excessive fetal mortality in Australia has also identified underutilisation and misinterpretation of fetal heart rate monitoring by "inadequately skilled" staff and a lack of "high quality staff education" as associated with preventable fetal morbidity and mortality. It is suggested that inadequate intrapartum fetal surveillance, and inadequate use or misinterpretation of cardiotocography contributed to excessive mortality, and part of this has been attributed to an inadequately skilled workforce (28, 29).

The work also goes towards redressing the dearth of published evidence of the cost effectiveness of different techniques and technologies of fetal monitoring. We are aware of only one published economic evaluation of CEFM in an Australian context (30). reported on a trial of 600 women randomised to CTG or fetal pulse oximetry (FPO), finding a non significant 23% relative risk reduction in operative delivery..

Strengths and limitations

A major strength of this research is the use of comprehensive prospectively collected patient data within the

context of a RCT, and the concurrently provided costing data. It is also the first RCT on STan as an adjunct to CTG in a region with a relatively higher CS rate, and hence, if there was adequate power, differences in the primary outcome, if they existed, were more likely to be demonstrated.

COVID-19 pandemic restrictions affected recruitment with limitations on non-critical activity mandated from March 2020. There was reluctance of midwives to recruit, and concerns from the women themselves, due to perceived invasiveness of the FSE and impairment of mobility resulting from the necessary use of a scalp clip if STan was randomised. This resulted in women 970 women completing the study, which was only 53% of the planned sample size. Thus, the study was underpowered to detect absolute differences </= 5% and the lack of a significant finding in the primary outcome (caesarean section) may have been due to a Type 2 error. Additionally, this failure to achieve the required power for clinical outcomes would may have adversely affected the power to detect differences in the economic outcomes.

Interpretation

Although no significant evidence of a reduction in maternal costs has been demonstrated, consistent indications of reduced neonatal costs associated with babies requiring less complex levels of care in the Stan+CTG arm suggest that this technology warrants further Australian and international research. As more data become available, it will be important to undertake meta-analyses, ideally including individual patient data, as well as updating existing reviews. These reviews will result in a stronger evidence base that should subsequently be used to formulate information for women about their options for fetal monitoring so that they can make informed decisions wherever practical. In the interim, given our previous findings of similarity in the main outcome (EmCS) and consistent patterns of cost reduction, we suggest that the addition of STan to CTG has the potential to be cost effective.

Conclusion

To conclude, the findings of reduced neonatal costs associated with the use of CTG+STan in an Australian context (ableit non-significant) are consistent with other studies performed elsewhere. Although no reduction of maternal costs has been demonstrated, and with no difference in the primary clinical outcome of emergency caesarean section, the reduced neonatal costs and the delivery of babies requiring less critical care suggest that the addition of STan to CTG warrants further investigation, and may be cost effective. STan may have a role in helping to address the significant safety challenges facing the maternity services.

Declarations

Author contribution

AS, DT, CW, IS, BM, SK, and GM conceived and designed the study and acquired funding. BS, SK, GM, CW, IS and DT managed the trial. CS, AS, BS, GM, SK and CW acquired the data. CS and AS analysed the data. CS, CW, AS, and DT wrote the draft of the article, and all authors reviewed, revised, and approved the final article.

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Ethical statement

The study was prospectively registered with the Australian Clinical Trials Registry (Australian Clinical Trial register number ACTRN12615001308583;)

Ethics approval was recieved from the Womens and Childrens Health Network Human Research Ethics Committee approval (HREC/14/WCHN/145). (approved 20/11/2017, last amendment approved 13/03/2019)

Disclosure of interest

Neoventa Medical (Mölndal, Sweden) provided training, education and engineering support for installation and use of the Neovental S31 machines, when STan was first introduced to the WCH as a standard of care in 2015, prior to and independent of the START RCT.

References

1. Kuah S, Simpson B, Salter A, Matthews G, Louise J, Bednarz J, et al. Comparison of effect of CTG + STan with CTG alone on emergency Cesarean section rate: STan Australian Randomized controlled Trial (START). Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology. 2023;62(4):462-70.

2. NHS Resolution. NHS Resolution Annual reports and accounts 2021 / 22. NHS Resolution, Care DoHaS; 2022 20 July 2022. Report No.: HC436 Contract No.: HC436.

3. Jauniaux E, Prefumo F. Fetal heart monitoring in labour: from pinard to artificial intelligence. BJOG : an international journal of obstetrics and gynaecology. 2016;123(6):870.

4. Alfirevic Z, Devane D, Gyte GM, Cuthbert A. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev. 2017;2:CD006066.

5. Bhide A, Chandraharan E, Acharya G. Fetal monitoring in labor: Implications of evidence generated by new systematic review. Acta obstetricia et gynecologica Scandinavica. 2016;85:5-8.

6. Davies.M, Lambert.G. Maternity payouts cost NHS twice the price of care itself. London Times. 2023 Saturday April 15 2023.

7. Wilkinson. C, Kuah. S, Bryson. K, Mayes. M, Matthews. G, Mol. B, et al. A pilot randomised trial of STan fetal monitoring compared with CTG monitoring alone. Journal of Paediatrics and Child Health. 2017;53 3–117.

8. Turnbull D, Salter A, Simpson B, Mol BW, Chandraharan E, McPhee A, et al. Comparing the effect of STan (cardiotocographic electronic fetal monitoring (CTG) plus analysis of the ST segment of the fetal electrocardiogram) with CTG alone on emergency caesarean section rates: study protocol for the STan Australian Randomised controlled Trial (START). Trials. 2019;20(1):539.

9. RANZCOG. Intrapartum Fetal Surveillance Clinical Guideline Clinical guideline [Internet]. 2019 [cited 2022 09/05/2022]; (Fourth edition). Available from: https://ranzcog.edu.au/news/intrapartum-fetal-surveillance-clinical-guideline.

10. Rosén. KG, Lindecrantz. K. STAN–the Gothenburg model for fetal surveillance during labour by ST analysis of the fetal electrocardiogram. . Clin Phys Physiol Meas 1989;10 51-6.

11. Amer-Wahlin I, Arulkumaran S, Hagberg H, Marsal K, Visser GH. Fetal electrocardiogram: ST waveform analysis in intrapartum surveillance. BJOG : an international journal of obstetrics and gynaecology. 2007;114(10):1191-3.

12. IHACPA. National Hospital Cost Data Collection 2023 [Available from: https://www.ihacpa.gov.au/health-care/costing/national-hospital-cost-data-collection.

13. Stata Statistical Software: Release 17. In: College Station TSLS, editor. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC. StataCorp. 2019. ed. College Station, TX: StataCorp LLC. StataCorp. 2019.; 2019.

14. Benton M, Salter A, Simpson B, Wilkinson C, Turnbull D. A qualitative study of a sample of women participating in an Australian randomised controlled trial of intrapartum fetal surveillance. Midwifery. 2020;83:102655.

15. Benton. M, Salter. A, Wilkinson. C, Simpson.B, Turnbull. D. Women's satisfaction with intrapartum fetal surveillance: a mixed-method study within the STan Australian Randomised Controlled Trial (START). . Midwifery (under review). 2023.

16. Benton. M, Salter. A, Wilkinson. C, Simpson. B, Turnbull. D. Psychosocial outcomes of a cohort of women participating in the STan Australian Randomised Controlled Trial (START). Birth (under review). 2023.

17. Westerhuis ME, Moons KG, van Beek E, Bijvoet SM, Drogtrop AP, van Geijn HP, et al. A randomised clinical trial on cardiotocography plus fetal blood sampling versus cardiotocography plus ST-analysis of the fetal electrocardiogram (STAN) for intrapartum monitoring. BMC pregnancy and childbirth. 2007;7:13.

18. Vayssiere C, David E, Meyer N, Haberstich R, Sebahoun V, Roth E, et al. A French randomized controlled trial of ST-segment analysis in a population with abnormal cardiotocograms during labor. American journal of obstetrics and gynecology. 2007;197(3):299 e1-6.

19. Westgate J, Harris M, Curnow JSH, Greene KR. Plymouth randomized trial of cardiotocogram only versus ST waveform plus cardiotocogram for intrapartum monitoring in 2400 cases. American journal of obstetrics and gynecology. 1993;169(5):1151-60.

20. van 't Hooft J, Vink M, Opmeer BC, Ensing S, Kwee A, Mol BW. ST-analysis in electronic foetal monitoring is cost-effective from both the maternal and neonatal perspective. The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstet. 2016;29(20):3260-5.

21. Schuit E, Amer-Wahlin I, Ojala K, Vayssiere C, Westerhuis ME, Marsal K, et al. Effectiveness of electronic fetal monitoring with additional ST analysis in vertex singleton pregnancies at >36 weeks of gestation: an individual participant data metaanalysis. American journal of obstetrics and gynecology. 2013;208(3):187 e1-e13.

22. E. W. Hospitals in England are told to stop using caesarean rates to assess performance. BMJ. 2022;376:o446. BMJ. 2022;376:446.

23. Secretary of State for Health and Social Care. The Government's response to the Health and Social Care Committee report

Safety of Maternity services in England: . HMSO; 2021.

24. Kirkup. B. Reading the signals. Maternity and Neonatal Services in East Kent. The report of the Independant Investigation. . 2022. Report No.: ISBN: 978-1-5286-3675-9.

25. Lintern S. Top midwife says sorry for lives lost to "normal birth" drive. The Sunday Times. 2022 Sunday March 6 2022;Sect. News.

26. Ockenden D. Ockenden Report Final Findings, conclusions and essential actions from the independant review of maternity services at the Shrewsbury and Telford Hospital NHS trust.: Her Majesties Stationery Office; 2022. Contract No.: E02725921 13/22.

27. Kirkup. B. The Report of the Morecambe Bay Investigation. Williams Lea Group UK: The Stationery Office; 2015. Contract No.: ID 26021502.

28. Picone. D, Pehm. K. Review of the Department of Health and Human Services' management of a critical issue at Djerriwarrh Health Services. Australian commission on quality and safety in health care; 2015 Nov 2015.

29. Wallace EM. Report of an investigation into perinatal outcomes at Djerriwarrh Health Services : Professor Euan M Wallace. Melbourne, Victoria Department of Health and Human Services; 2016. Contract No.: 4753594 (ISMN).

30. East CE, Gascoigne MB, Doran CM, Brennecke SP, King JF, Colditz PB. A cost-effectiveness analysis of the intrapartum fetal pulse oximetry multicentre randomised controlled trial (the FOREMOST trial). BJOG : an international journal of obstetrics and gynaecology. 2006;113(9):1080-7.

Table 1: Hospital costs over 6 weeks, across armsintention to treat; ITT): total and per mother/ baby dyad

Hospital Costs	**ITT analysis set** (956 dyads)	**CTG+Stan** (476 dyads)	**CTG** (480 dyads)	**Cost difference (CI 95%), p value**
Operating Theatre and SPS	$1,241	$1,250	$1,232	$17 (-$244, $278) p=0.45
Ward Nursing	$4,572	$4,510	$4,634	-$124 (-$515, $266) p=0.27
Ward medical	$1,661	$1,540	$1,781	-$241 (-$620, $544) p=0.06
Pharmacy, prostheses and ward stores[a]	$1,506	$1,470	$1,541	-$72 (-$193, $48) p=0.12
Critical Care	$810	$177	$1,438	-$1,261 (-$3,299, $778) p=0.11
Imaging and/or Pathology	$442	$411	$473	-$62 (-$155, $31) p=0.10
Allied Health	$185	$149	$222	-$73 (-$181, $36) p=0.10
Transport	$57	$6	$108	-$102 (-$300, $97) p=0.16
Other[b]	$3,428	$3,256	$3,599	-$343 (-$837, $150) p=0.09
Total costs	$13,289,928	$6,077,019	$7,212,909	
Costs per mother/baby dyad	Costs per mother/baby dyad	Costs per mother/baby dyad	Costs per mother/baby dyad	Costs per mother/baby dyad
Mean	**$13,902**	**$12,768**	**$15,027**	**-$2,260** (-$5,482, $962), p=0.08
(95% CI)	($12,290, $15,514)	($11,968, $13,565)	($11,913, $18,141)	
25% percentile	$7,227 $10,812	$7,176 $10,905	$7,287 $10,638	
50% percentile (median)	$16,128	$16,060	$16,238	
75% percentile				

[a] Pharmacy includes: pharmacy and PBS drugs, prostheses and ward stores

[b] Other includes: depreciation, hotel costs, non-clinical costs and on-costs

Table 2: Maternal and neonatal admissions and readmissions*, with hospital costs

	ITT analysis set n (%)	**CTG+STan** n (%)	**CTG** n (%)	**Risk difference (95% CI), and/or test , p value**
Maternal admissions				-
Number of maternal admissions (for delivery)	956	476	480	
Maternal readmissions	**Maternal readmissions**	**Maternal readmissions**	**Maternal readmissions**	**Maternal readmissions**
Number of maternal readmissions	24	14	10	
Mothers with [?]1 admission	23 (2.41%)	13 (2.73%)	10 (2.08%)	0.65% (-1.30%, 2.59%), Fisher's exact 2 sided p = 0.54
Mothers with [?]2 admissions	1 (0.10%)	1 (0.21%)	0 (0.00%)	0.21% (-0.20%, 0.62%), Fisher's exact 2-sided p = 0.50
Neonatal admissions	**Neonatal admissions**	**Neonatal admissions**	**Neonatal admissions**	**Neonatal admissions**
Number of neonatal admissions	375	175	200	
Neonatal readmissions				
Neonates with [?]1 admission	331 (34.62%)	161 (33.82%)	170 (35.42%)	-1.59% (-7.62%. -4.44%) Fisher's exact (2 sided) p = 0.634
Neonates with [?]2 admissions	34 (3.56%)	10 (2.10%)	24 (5.00%)	**-2.90% (-0.562%, -5.24%)** Fisher's exact (2-sided) **p = 0.022**
Neonates with a critical care admission	21 (2.20%)	7 (1.47%)	14 (2.92%)	-1.45% (-3.30%, 0.41%) Fisher's exact (2 sided) p = 0.184
Total admissions recorded	1,355	665	690	
Delivery Admission	**Delivery Admission**	**Delivery Admission**	**Delivery Admission**	**Delivery Admission**
Total Costs	$9,853,438	$4,932,482	$4,920,956	
Average per dyad	$10,307	$10,362	$10,252	$110 (-$527, $747), p = 0.37
Maternal readmissions	**Maternal readmissions**	**Maternal readmissions**	**Maternal readmissions**	**Maternal readmissions**

	ITT analysis set n (%)	**CTG+STan** n (%)	**CTG** n (%)	**Risk difference (95% CI), and/or test , p value**
Total maternal readmission costs (n mothers readmitted)	$99,383 (23)	$67,438 (13)	$31,945 (10)	
Average cost per mother with readmission	$4,321	$5,188	$3,194	$1,993 (-$575. $4,562), p = 0.06
Average maternal readmission costs per dyad in cohort	$104	$142	$67	**$**75 (-27, $178), p = 0.08

Based on costings data, not as reported in clinical analysis

Table 3: Average costs, by admission type, excluding outlier mother/baby dyad

Admission Component	**ITT, less outlier** (955 dyads)	**CTG+STan** 476 dyads	**CTGalone** 479 dyads	**Difference, (CI 95%), p value**
Delivery cost (per dyad in cohort)	$10,309	$10,362	$10,257	$106 (-$532, $743), p = 0.4
Maternal readmission cost (per dyad in cohort)	$104	$142	$67	$75 (-$28, $178), p = 0.08
Neonatal admission cost (per dyad in cohort)	$2,748	$2,263	$3231	**-$968 (-$2,139, $203), p =0.053**
Neonatal ICU cost (per dyad in cohort)	$296	$158	$432	-$274 (-$753, $205), p=0.13
Average total cost, per dyad	**$13,162**	**$12,767**	**$13,554**	-$788 (-$2,190, $615), p = 0.14

Table 4: Admission rates and average costs, by per-protocol (PP) analysis

	PP* analysis set	**CTG+STan**	**CTG alone**	**Difference, (CI 9**
Delivery Admissions (dyads)	872	393	479	
Mothers with readmission(s)	19	9 (2.29%)	10 (2.09%)	0.20%, Fisher's exa
Neonates with admission(s)	296	126 (32.06%)	170 (35.49%)	-3.43% Fisher's exa
Neonatal ICU admissions 2 sided p= 0.009	16	2 (0.51%)	14 (2.92%)	**-2.41% Fisher's e**
Delivery cost (per dyad in cohort)	$10,299	$10,347	$10,260	$87 (-$578, $752),
Maternal readmission cost (per dyad in cohort)	$83	$104	$67	$37 (-$50, $124), p
Neonatal admission cost (per dyad in cohort)	$3,405	$1,805	$4,718	**-$2,913 (-$6,332,**

	PP* analysis set	CTG+STan	CTG alone	Difference, (CI 9
Neonatal ICU cost (per dyad in cohort)	$809	$39	$1,441	-$1,402 (-$3,643, $8
Total average cost, per dyad	**$13,788**	**$12,256**	**$15,045**	-$2,789 (-$6290, $7

* Includes only those participants who undertook the fetal monitoring they were randomly assigned to receive

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