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RESEARCH

Effects of algorithm for diagnosis of active labour: cluster randomised trial

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ABSTRACT

Objective To compare the effectiveness of an algorithm for diagnosis of active labour in primiparous women with standard care in terms of maternal and neonatal outcomes.

Design Cluster randomised trial.

Setting Maternity units in Scotland with at least 800 annual births.

Participants 4503 women giving birth for the first time, in 14 maternity units. Seven experimental clusters collected data from a baseline sample of 1029 women and a post-implementation sample of 896 women. The seven control clusters had a baseline sample of 1291 women and a post-implementation sample of 1287 women.

Intervention Use of an algorithm by midwives to assist their diagnosis of active labour, compared with standard care.

Main outcomes Primary outcome: use of oxytocin for augmentation of labour. Secondary outcomes: medical interventions in labour, admission management, and birth outcome.

Results No significant difference was found between groups in percentage use of oxytocin for augmentation of labour (experimental minus control, difference=0.3, 95% confidence interval −9.2 to 9.8; P=0.9) or in the use of medical interventions in labour. Women in the algorithm group were more likely to be discharged from the labour suite after their first labour assessment (difference= −19.2, −29.9 to −8.6; P=0.002) and to have more pre-labour admissions (0.29, 0.04 to 0.55; P=0.03).

Conclusions Use of an algorithm to assist midwives with the diagnosis of active labour in primiparous women did not result in a reduction in oxytocin use or in medical intervention in spontaneous labour. Significantly more women in the experimental group were discharged home after their first labour ward assessment.

Trial registration Current Controlled Trials ISRCTN00522952.

INTRODUCTION

Women are often uncertain about the onset of labour and timing their hospital admission,[1-4] and this uncertainty may also extend to midwives and obstetricians. Although superficially straightforward, diagnosis of labour has been described as one of the most difficult and important judgments in the care of a woman in labour.[5] Evidence shows that misjudgments are often made: between 30% and 45% of women admitted to labour wards in the United Kingdom and other developed countries are subsequently found not to be in labour.[6-8] These admissions may have important clinical consequences. Several studies have shown that women admitted in the latent phase or not yet in labour are more likely to receive medical intervention (electronic monitoring, epidural analgesia, oxytocin, and caesarean section) than those admitted in active labour.[8-11] The widespread use of routine medical intervention in labour is of worldwide concern.[12-15] Caesarean section rates as high as 80% have been reported among some groups.[16] In England, only 46% of women experience normal birth—that is, birth without surgical intervention, use of instruments, induction, augmentation with oxytocin, epidural, or general anaesthetic.[17] Interventions in labour have been associated with increased levels of morbidity and mortality for mothers and babies,[18-21] and reduction in the overall rate of intervention in labour is an international healthcare target.[22 23]

A possible reason for the higher rate of intervention in women admitted early is that clinicians do not make an accurate distinction between women who are in active labour and those who are not yet in labour or who are in the latent phase.[8-11] This may be because they misdiagnose active labour or because they use labour ward admission itself as a proxy measure for active labour. Once admitted, the mere presence of a woman in the labour ward over a protracted period of time may encourage caregivers to intervene.[24] Supporting clinicians' judgments about diagnosis of labour by providing explicit diagnostic cues has the potential to reduce unnecessary admissions to the labour ward and correspondingly the rate of intervention in labour.

Although diagnostic cues for labour have been described,[7 25-31] only one randomised controlled trial has tested the efficacy of adhering to strict criteria for diagnosis of labour.[30] This study reported a reduction

in the use of augmentation with oxytocin and analgesics. The study was small, however, and a Cochrane review concluded that a multicentre randomised controlled trial was needed to determine the risks and benefits of using explicit criteria to diagnose active labour.[5]

The Medical Research Council suggests a framework for developing and evaluating randomised controlled trials for complex healthcare interventions.[32] We followed this framework in conducting a series of studies to explore the diagnosis of labour from the perspective of midwives and women and a needs assessment for an intervention to support midwives' diagnosis of labour.[4 33 34] We chose midwives because they are the professional group responsible for the admission of healthy women in labour in the UK. We chose a decision support approach because evidence shows that decision aided judgments consistently outperform clinical judgment alone.[35 36] Furthermore, the MRC framework stresses the importance of defining the trial intervention, and this is particularly important in a trial involving multiple sites. We therefore chose to structure the diagnostic cues for labour in the form of an algorithm, thus ensuring (as far as possible) that the intervention would be applied in a standard fashion across trial sites.

We hypothesised that improving the diagnosis of labour in primiparous women through the use of an algorithm would result in a reduction in the use of oxytocin for augmentation of labour and other labour interventions compared with standard care. We chose a cluster randomised trial for this purpose because the algorithm was aimed at the clinical practice of midwives. We could not use individual randomisation of women or midwives because of the risk of contamination between groups. The results of a health economics evaluation, done as part of the cluster randomised trial, will be presented elsewhere.

METHODS

Recruitment and randomisation

The trial took place between April 2005 and June 2007. Three levels of participation existed: the unit of randomisation was the maternity unit, midwives were participants at the level of the intervention, and we measured trial outcomes for women receiving maternity care.

Maternity units in Scotland with at least 800 annual births were eligible to participate in the trial. These units had the facilities to provide oxytocin for augmentation of labour.[37] After discussion with heads of midwifery and other stakeholders at each unit, clinical directors gave consent for trial entry. Thereafter, we used minimisation to allocate maternity units to experimental or control groups.[38] After random allocation of the first maternity unit, we purposively allocated clusters in order to maximise balance between groups. We chose presence or absence of an on-site midwife managed birth unit as the balancing variable, because the philosophy of care within a midwife managed birth unit would be one of low

medical intervention and this could correlate with a lower use of oxytocin. JMB did the group allocation and was not involved in recruitment. Study implementation was staged to allow time for training of midwives, with a data collection period of up to 10 months in each maternity unit. A clinical midwife in each unit was responsible for facilitating study implementation and collecting trial outcome data from case records.

In the experimental group, we invited midwives who admitted women in labour to participate in the study. We provided workshops and individual contacts for each midwife, and each received a training manual. This included information on how to use the algorithm, the cluster trial method, completion of study documentation, and seeking consent from women in labour. Thereafter, we asked midwives to consent to study

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Study entry criteria

Inclusion criteria

Women presenting for admission in spontaneous labour and fulfilling the following criteria:

- Primiparous
- Singleton pregnancy
- Cephalic presentation
- 37-42 weeks' gestation
- Current pregnancy uncomplicated

Exclusion criteria

- Girls under 16
- Women with learning difficulties
- Severely ill women
- Women with severe mental illness
- Women with important medical problems:

  Essential hypertension

  Cardiac disease

  Renal disease

  Diabetes

  Endocrine disease

  Epilepsy

  History of thromboembolism

  Asthma (that is, regular use of inhalers)

  Drug or alcohol abuse

- Women with current pregnancy complications:

  Haemoglobin <9.0 g/dl

  Platelets <100×10/l

  Antepartum haemorrhage

  Pregnancy induced hypertension

  Fetal death

  Fetal abnormality

  Polyhydramnios >25 cm

  Oligohydramnios >5 cm

  Current intrauterine growth retardation—that is, less than 5th centile

  Booking weight of 47 kg or less/100 kg or more
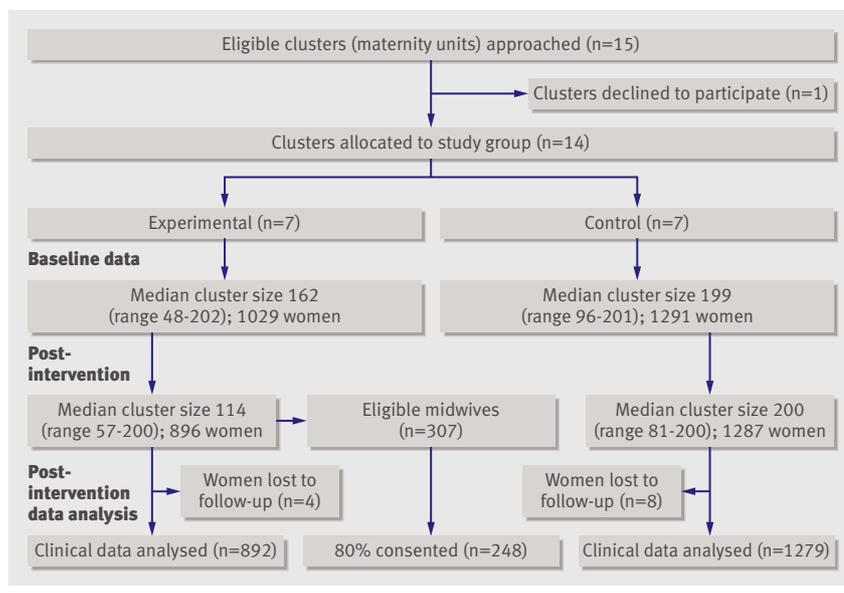
Fig 1 | Trial profile.

participation. We made minimum contact with midwives in control units to reduce the potential for a Hawthorne effect.[39]

We considered women to be eligible for recruitment if they attended a participating maternity unit for assessment of labour and were primiparous, at term, and assessed as low risk on the basis of criteria used in previous intrapartum studies (box).[40-42] We used the same eligibility criteria in both experimental and control groups. In order to reduce confounding variables, we excluded multiparous women from the trial. Although the principles of diagnosis of labour are the same for both primiparous and multiparous women, differences exist in the way in which their labour would be expected to progress. Furthermore, a woman's previous experience of labour will influence her intrapartum care.

Women in both arms of the trial were given information at a clinic visit between 34 and 36 weeks' gestation. Women were required to give consent for use of the algorithm and collection of identifying data (needed for distribution of the health economics questionnaire). However, because the trial intervention was the assessment of labour on admission, consent had to be obtained differently in experimental and control groups. In the experimental group, the admitting midwife identified eligible women on admission to the labour suite and provided written and verbal explanations of the study and asked for consent. This approach could not be used in control groups without involving labour ward midwives in providing information about the trial and thus contaminating the group, so women in the control group were asked for consent in the postnatal wards. We asked midwives to recruit women who would have been eligible for the trial when they first presented for labour admission, regardless of subsequent labour outcome. Although blinding of midwives was not

possible, only midwives in the experimental group had access to the algorithm and minimum information about the study was available to control units.

Intervention

The process of development and pre-testing of the algorithm is described elsewhere.[33 34 43] The algorithm comprised three levels: level one confirmed the woman's eligibility for involvement in the study (that is, a healthy primiparous woman with a normal, term pregnancy); level two prompted a general physical assessment (for example, temperature, pulse, and blood pressure); and level three presented, in a stepwise fashion, key informational cues needed for diagnosis of labour. Active labour was diagnosed when painful, regular, moderate or strong uterine contractions were present (on the basis of the midwives' clinical assessments), as well as at least one of the following cues: cervix effacing and at least 3 cm dilated, spontaneous rupture of membranes, or "show." We rigorously pre-tested the algorithm with three samples of midwives by using questionnaires and vignettes and found it to have good face validity and content validity and a high level of inter-rater reliability.[43] Subsequently, we did a feasibility study in two maternity units. This showed that the implementation strategy and methods for the cluster randomised trial were feasible and acceptable to midwives and women.[34] Midwives reported that the algorithm was acceptable and potentially useful, particularly for inexperienced midwives.

Context

All units that participated in the trial were consultant led maternity units with a range of neonatal facilities (table 1), as classified by the report of the expert group on acute maternity services in Scotland.[37] The predominant model of care in all of these units encouraged women to contact their maternity unit, by telephone, for advice when they thought that they were in labour and then to attend the maternity unit for admission assessment. In all of the units the labour assessment for most women was done in either the labour ward or a designated assessment area. During the trial, women in both groups contacted the hospital and then attended for assessment in a similar way.

Trial groups

Experimental—In the experimental group, we asked midwives to use the algorithm during the admission assessment of women to assist in the diagnosis of active labour, recording their judgment on the algorithm. The algorithm was printed on duplicate paper; once completed, one part was retained in the woman's case record and the other was collected by the local study coordinator. Women identified as not yet in active labour were encouraged to return home or were admitted to an antenatal area, depending on local maternity unit policy.

Control—Eligible women who attended for admission assessment in the control group units received normal care. This comprised admission assessment by midwives using clinical judgment alone. Although standard care varied between control units, none had guidelines or protocols for diagnosis of labour at the time of this study. Owing to the Scotland-wide, multisite nature of the trial, dictating where the woman should go after the admission assessment was not appropriate. Some units served remote and rural areas, in which women may have travelled for several hours to reach the maternity unit. In such cases, women may have had difficulty returning home. Therefore, after the admission assessment, women in both groups received standard care for their maternity unit.

Outcomes

The primary outcome was use of oxytocin (any dose) for augmentation of labour. Women who are admitted during the latent phase of labour are more likely to be diagnosed as having slow progress in labour.[8-11] We chose oxytocin as the primary outcome because it is the principal treatment (and key marker) of slow progress in labour. Furthermore, primiparous women who receive oxytocin have a reduced likelihood of an unassisted vaginal delivery.[44] The use of explicit criteria for admission in labour has been associated with a significant reduction in use of oxytocin in labour.[5] Secondary outcomes were interventions in labour (artificial rupture of membranes, vaginal examination, continuous electronic fetal monitoring, and use of analgesia), admission management (number of admissions before labour, time spent in labour ward,
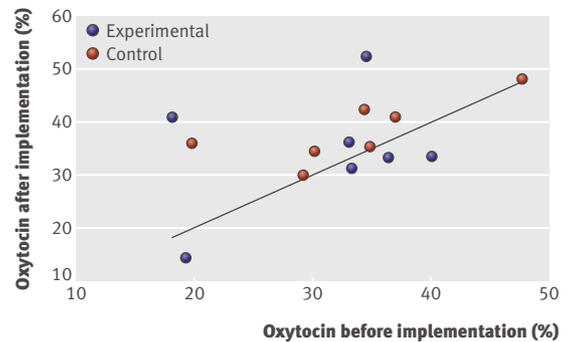

Fig 2 | Oxytocin use before and after trial implementation

and duration of active labour), and labour outcomes (mode of delivery, intrapartum complications, neonatal outcome, and unplanned out of hospital births).

Data collection

We collected study outcome data from a sample of case records at baseline and a second sample after implementation of the study. We collected baseline data retrospectively from the case records of 200 women who gave birth in each unit before implementation of the study and who fitted the trial eligibility criteria on first labour ward assessment. These data were anonymised. We collected data for the post-implementation sample from case records after delivery.

A secretary based in the research unit entered all data and monitored returns to ensure that recruitment was meeting agreed milestones. We audited data forms (10%) and found 88% accuracy of data entry; 12% of cases had one data entry error, which was corrected. We established an independent data and safety monitoring committee to monitor the occurrence of severe adverse incidents relating to the study. No such incidents occurred.

Sample size

The statistical power calculation was appropriate for an unmatched cluster randomised design. The feasibility study showed the rate of oxytocin use in primiparous women in spontaneous labour to be more than 40% in several units in Scotland, with a mean of 34%. We calculated the intracluster correlation coefficient to be 0.041. The multidisciplinary trial steering group deemed a difference of 10 percentage points (for example, from 40% to 30%) in the proportion of women receiving oxytocin to be clinically relevant. Because only a maximum of 15 maternity units were available, simply comparing intervention and control groups could not achieve sufficient power to detect this difference. We therefore used baseline data for the maternity unit to reduce the effect of variation between units. We noted the proportion of women given oxytocin before and after study implementation and used the proportion before implementation as a covariate in an analysis at the level of the maternity unit. From the feasibility study data the study

Table 1 | Characteristics of participating units by cluster*

Unit No	Total annual births	Birth unit	Unit type*	Labour suite midwives	Midwives' consent (%)
Experimental (n=19 410)					
2	3166	No	11c	30	102† (100)
4	1305	No	11c	48	31 (65)
7	3324	Yes	11c	27	Missing data
9	1888	No	11c	33	31 (94)
10	950	No	11b	39	25 (64)
12	5242	Yes	111	61	35 (57)
14	3535	No	111	26	24 (92)
Control (n=20 682)					
1	1042	No	11b	NA	NA
3	2988	No	11c	NA	NA
5	4183	Yes	111	NA	NA
6	3426	No	111	NA	NA
8	3590	No	11c	NA	NA
11	2710	Yes	11c	NA	NA
13	2743	No	11c	NA	NA

NA=not applicable.

*11b=consultant led maternity unit with on-site special care baby unit and annual births <1000; 11c=consultant led maternity unit with easy access to neonatal intensive care, adult high dependency, and adult intensive care and annual births 1000-3000; 111=consultant led specialist maternity unit with on-site neonatal intensive care, access to adult intensive care, and annual births >3000.

†Recruitment seems to exceed total number of midwives in one cluster because team model of midwifery care was operating in that unit; this meant that most hospital and community based midwives had labour suite commitment during study period.

statistician (JMB) estimated that the correlation between proportions would be 0.89, by using data for 200 women before and 200 after implementation of the study in each unit. We used these estimates in the Stata 8 sampsi command to estimate a study power of 0.97 for detecting a 10 percentage point difference in oxytocin use at a significance level of 0.05 "after" oxytocin use, with a total of at least 12 hospitals with 200 women observed before and 200 after the trial implementation point.

Analysis

Data analysis was appropriate for a cluster randomised trial and accounted for clustering of observations within maternity units. In practice, a woman may receive care from several midwives, so we did all analysis at the level of the unit or the woman. The primary analysis used multiple regression of maternity unit level data adjusted for baseline. This meant that for each outcome we calculated a summary statistic (the mean or proportion) for each cluster, at baseline and after study implementation. In each case, the baseline value was the covariate. This provided a confidence interval and test of significance for the difference in proportions of women receiving oxytocin. We did other analyses at the level of the individual woman or using data aggregated to cluster level as appropriate.

RESULTS

Of the 16 eligible maternity units in Scotland, one had participated in the feasibility study. We approached the remaining 15 units, of which 14 agreed to participate and were allocated to experimental or control groups. One unit declined because of other research commitments (fig 1). Once entered, all units completed the trial as allocated. Table 1 gives a description of the units.

Most units in both groups were classified as 11c on the basis of the classification of the expert group on acute maternity services in Scotland,[37] and annual births ranged from 950 to 5242. Two units in each group had an on-site midwife managed birth unit. Overall, 80% of midwives consented to participate (unit range 57-100%). Baseline data were collected for 1029 women in the experimental group and 1291 women in the control group (fig 1).

The steering group did a routine review of study procedures after the first few months of data collection and recommended a protocol change to minimise any potential risk of selection bias in the control group. Midwives might have been reluctant to approach women who had experienced complications of labour or negative outcomes. We asked midwives in the control group to continue to recruit women as planned up to a sample of 100 women, needed for the health economics evaluation questionnaire. We asked them to then go back to the recruitment start date and review the case records of women who had given birth from that time and who had been eligible but not recruited. Anonymous study outcome data were collected from consecutive cases up to the total target sample of 200 cases. This resulted in near complete data collection in control units. This strategy was not needed in experimental sites, where all women were recruited prospectively on admission to labour suites. The second sample, recruited after implementation of the study, comprised 896 women from experimental units and 1287 cases from the control units (these cases comprised women who consented postnatally and the anonymously collected data). A small amount of information was lost to follow-up from the post-implementation sample owing to inability to retrieve case records (four in the experimental group and eight in the control group) (fig 1). We thus analysed data for 892 women in the experimental group and 1279 women in the control group.

Table 2 shows the flow of data by cluster. We estimated the number of potentially available women from routinely collected national data.[45 46] This gives the number of women who would have been potentially eligible for recruitment during the planned 10 month data collection period after implementation of the trial in each cluster. The Information Services Division of NHS National Services Scotland provides national data by health board area, so local variations in maternity activity are included. The smallest units (in terms of annual births) did not necessarily have the fewest number of women who were potentially eligible for the trial. We asked units to recruit 200 women after implementation of the trial, but only nine units managed this. Although the data on potentially eligible women are estimates, they suggest that the smallest units experienced difficulty in recruiting the target sample within the trial period.

Table 3 shows cluster level data for the primary outcome. Figure 2 shows the proportion of women given oxytocin for augmentation of labour in each cluster at baseline and post-implementation. We found

Table 2 | Flow of data by cluster

Unit No	Estimated available women in 10 months	Baseline data (target 200)	After study implementation (target 200)	After study implementation data analysed
Experimental				
2	642	198	200	200
4	138	48	65	64
7	731	83	57	56
9	355	202	200	199
10	156	200	60	60
12	578	162	200	200
14	550	136	114	113
Total	3150	1029	896	892
Control				
1	248	201	200	200
3	402	199	200	199
5	842	199	200	200
6	348	200	200	200
8	769	199	200	200
11	538	197	200	200
13	555	96	81	80
Total	3702	1291	1287	1279

Table 3 | Oxytocin use "before" and "after" study implementation

Unit No	Total women per cluster (before and after)	Oxytocin use—% (No)	
		At baseline	After study implementation
Experimental (n=1921)			
2	398	18 (36/198)	41 (82/200)
4	112	33 (16/48)	31 (20/64)
7	139	19 (16/83)	14 (8/56)
9	401	40 (81/202)	34 (67/199)
10	260	37 (73/200)	33 (20/60)
12	362	35 (56/162)	53 (105/200)
14	249	33 (45/136)	36 (41/113)
Control (n=2570)			
1	401	35 (70/201)	36 (71/200)
3	398	48 (95/199)	48 (96/199)
5	399	29 (58/199)	30 (60/200)
6	400	37 (74/200)	41 (82/200)
8	399	30 (60/199)	35 (69/200)
11	397	20 (39/197)	36 (72/200)
13	176	34 (33/96)	43 (34/80)

no significant difference in the percentage of oxytocin use attributable to the application of the algorithm (difference=0.3, 95% confidence interval −9.2 to 9.8; P=0.9).

For secondary outcomes, we present summary descriptive data for experimental and control groups at baseline (before) and post-intervention (after): these data do not take account of the effect of clustering. We then used regression to analyse data for each outcome, taking account of clustering. We adjusted the difference between groups (experimental minus control) for baseline and clustering. We found no significant difference between groups for any of the labour interventions considered: artificial rupture of membranes, continuous electronic fetal monitoring, use of pain relief, and vaginal examination (table 4).

Significantly more women in the control group had only one admission (table 5), meaning that women in the control group were more likely to remain in the labour suite after their first admission assessment until delivery. In contrast, women in the experimental group were significantly more likely to have several admissions and discharges before their eventual admission leading to delivery.

We found no significant difference between groups for duration of active labour, time from the first labour

assessment to delivery, or time from final admission to labour suite until delivery (table 6). The mean duration of active labour exceeded the mean time from admission to delivery because active labour started before admission in several cases. Table 7 shows additional descriptive data on mean time from final admission to delivery and duration of active labour by the number of admissions before labour. We did no statistical analysis, as the number of previous admissions was an outcome variable.

We found no significant difference in mode of delivery between study groups (table 8). Overall, 45% (n=2028) of women had at least one intrapartum complication. We made statistical comparisons only for complications that occurred in at least 100 cases, as with fewer cases we could not allow for clustering. We found no significant difference in maternal complications between groups.

Table 9 shows neonatal outcomes. Overall, 67 babies were admitted to the neonatal unit for more than 48 hours, but this did not differ significantly between groups. Very few unplanned out of hospital births or babies with an Apgar score less than 7 at five minutes occurred, so we did no statistical analysis for these variables. One stillbirth occurred in the control group at baseline.

DISCUSSION

This trial, involving 14 maternity units and 4503 women, tested the effectiveness of an algorithm to assist midwives with the diagnosis of active labour in primiparous women. We found that use of the algorithm did not reduce the number of women who received oxytocin or other medical interventions compared with standard care. Significantly more women in the control group remained in the labour ward until delivery after their first admission, whereas women in the experimental group were more likely to be discharged home and subsequently have significantly more admissions before labour. We found no significant difference between groups in the length of time from the first labour ward assessment until delivery, time spent in the labour suite during labour, or duration of active labour. No significant difference existed between groups for maternal or neonatal complications or unplanned out of hospital births.

Although we found no significant difference in the primary outcome, the strength of the study design

Table 4 | Interventions in labour. Values are numbers (percentages) unless stated otherwise

Intervention	Experimental		Control		Difference* (95% CI)	P value
	Before (n=1029)	After (n=892)	Before (n=1291)	After (n=1279)		
Artificial rupture of membranes	383 (37.2)	401 (44.9)	514 (39.8)	500 (39.0)	5.6 (−2.2 to 13.4)	0.1
Continuous electronic fetal monitor	567 (55.1)	557 (62.4)	781 (60.4)	820 (64.1)	−0.1 (−14.2 to 14.1)	1.0
Epidural	211 (20.5)	290 (32.5)	382 (29.5)	441 (34.4)	2.1 (−8.0 to 12.2)	0.7
Opiate	646 (62.7)	532 (59.6)	680 (52.6)	649 (50.7)	1.5 (−4.6 to 7.6)	0.6
Epidural and opiate	129 (12.5)	177 (19.8)	223 (17.2)	225 (17.5)	4.4 (−2.8 to 11.7)	0.2
Vaginal examination mean (range)	2.89 (0-11)	3.67 (0-11)	3.31 (0-10)	3.46 (0-11)	0.2 (−0.3 to 0.7)	0.3

*Data analysis took into account clustering and adjusted for baseline.

Table 5 | Number of admissions. Values are numbers (percentages) unless stated otherwise

Admissions	Experimental		Control		Difference	P value
	Before (n=1029)	After (n=892)	Before (n=1291)	After (n=1279)		
One admission	617 (60.0)	398 (44.6)	798 (61.8)	795 (62.6)	−19.2 (−29.9 to −8.6)	0.002
Mean (range) admissions	1.28 (1-4)	1.45 (1-4)	1.26 (1-4)	1.28 (1-6)	0.29 (0.04 to 0.55)	0.03
No of admissions before labour:						
1	308 (29.9)	305 (34.1)	382 (29.5)	366 (28.6)	NA	NA
2	79 (7.6)	149 (16.7)	85 (6.5)	88 (6.8)	NA	NA
3	14 (1.3)	32 (3.5)	16 (1.2)	17 (1.3)	NA	NA
≥4	2 (0.01)	3 (0.3)	3 (0.2)	3 (0.2)	NA	NA
Missing data	9	5	7	10	NA	NA

NA=not applicable.

means that it makes an important contribution to the debate on early labour management. The diagnosis of labour has important clinical and resource implications for the care of a woman in labour, but only one other trial has specifically evaluated the efficacy of using strict diagnostic criteria.[30] In contrast to our findings, this trial reported that when labour was assessed by using strict diagnostic criteria significantly fewer women received oxytocin to augment labour (22.9% v 40.4%) compared with no labour assessment and less pain relief was used (7.6% v 20%). Although both trials included similar diagnostic criteria, the interventions were not identical. In the study by McNiven et al, low risk women were randomly allocated when they presented in spontaneous labour.[30] All women in the control group were admitted directly to the labour ward without assessment of labour, whereas women in the experimental group had their labour assessed with strict criteria; those judged not to be in labour were sent home or remained in an assessment area to await the establishment of active labour before being admitted to the labour ward. McNiven et al thus evaluated a package of care that included both diagnosis and management of early labour.[30] In the trial reported here, midwives in both experimental and control groups carried out a clinical assessment of women before admission to the labour suite. In the experimental group this assessment was supported by the algorithm. In both groups, decisions about subsequent clinical management were determined by the midwives (women could be admitted or discharged home). Therefore, the groups differed only in the use of the algorithm; this may have contributed to the difference

in findings compared with those of McNiven et al.[30] The principal difference between the studies is, however, in design and scale. McNiven et al's study took place in one hospital with 209 women and was underpowered to test the effects of the intervention on several important maternal and neonatal outcomes.[30] As our study included 14 maternity units and data on 4503 women, the results are more likely to be an accurate estimate of the effect of using explicit diagnostic cues for active labour on the rate of oxytocin use.

This highlights the importance of both study power and design. Although the target recruitment of 12 maternity units with an overall target sample of 400 in each unit (200 before and 200 after implementation of the trial) was not achieved at all sites, this deficit was partially offset by the recruitment of an additional two maternity units. The use of baseline data to reduce the in-hospital variation was a methodological development in this trial. The correlation between the percentage of women receiving oxytocin before and after the intervention was 0.46, which was less than the 0.89 originally estimated from data collected during the feasibility study and this reduced the power of the study (changes within the units may have occurred over time and reduced the correlation). Nevertheless, reflecting with hindsight on the success of this method we can conclude that the study had sufficient power to test the primary outcome; the 95% confidence interval for the difference in percentage use of oxytocin was −9.2 to 9.8, which excludes the difference of 10 percentage points we had chosen as the difference that would be of clinical relevance.

Table 6 | Time in labour ward and duration of active labour. Values are mean (SD) unless stated otherwise

Time in labour (hours)	Experimental		Control		Difference	P value
	Before (n=1029)	After (n=892)	Before (n=1291)	After (n=1279)		
Admission to delivery	8.08 (5.68)	9.60 (11.29)	7.81 (5.07)	8.06 (5.41)	0.75 (−0.55 to 2.05)	0.2
Missing data (No)	109	51	98	77		
Duration of active labour	9.91 (5.35)	10.82 (5.52)	9.55 (4.96)	9.54 (5.17)	0.61 (−0.45 to 1.67)	0.2
Missing data (No)	145	69	112	98		
Time from first admission assessment to delivery	30.2 (115.0)	29.3 (97.5)	34.7 (154.2)	33.3 (152.3)	−0.1 (−14.2 to 14.0)	0.988
Missing data (No)	79	37	70	62		

The fact that this is the first adequately powered study to assess the impact of diagnostic cues in early labour management is in itself a success. Healthcare professionals need robust evidence on which to draw in making decisions about clinical care. Studies of complex interventions that are then tested in complex care systems are challenging, particularly when a multi-site trial is needed. We followed the MRC framework for the development of randomised controlled trials of complex healthcare interventions, doing a series of pilot and feasibility studies before the cluster trial reported here. However, the science of trial development for complex interventions is constantly changing; since the inception of this trial, the importance of carrying out process evaluations concurrently within the trial itself (rather than in the development stages of the trial as in this study) has been recognised.[47] Such an evaluation may have provided an explanation of the finding of no difference between groups for the primary outcome. It is a characteristic of complex systems (such as maternity units) that even a simple intervention may have unpredictable effects on the processes and outcomes of care.[48] Therefore, the act of doing a process evaluation during the course of a trial may in itself alter practice, thus confounding the results of the study. These factors need careful consideration during the design stages of trials of complex interventions.

Limitations of the trial

We could not accurately determine the number of eligible women in each maternity unit, and estimates were based on routinely collected data (table 2). These data were available by hospital, for primiparous women at term, with a singleton pregnancy, in spontaneous labour, and over 16 years. However, we could not identify the number of women who would have been ineligible for medical or obstetric reasons, nor could we differentiate between women who were not eligible and those who were not approached for consent to data collection. During the feasibility study, 85% of women approached gave consent, so women not included were probably not approached. Although almost all eligible women in some of the smaller units seemed to have been included, in most of the units the proportion of eligible women not included was high and therefore selection bias could have occurred. The strength of the cluster design is that it avoids contamination between groups; however, the design is prone to selection bias,[49] because consent to trial entry is given at cluster level but individuals can then decide whether to accept or refuse the trial intervention. Selection bias is also a common problem in trials of intrapartum care, in which difficulty in estimating numbers of potentially eligible participants and high losses to recruitment are often reported.[50] Intrapartum trials often rely on clinical staff to seek consent from women who are in labour. This method is practical in recruiting women close to the point of study intervention, but recruitment is vulnerable to practitioners both making clinical judgments about which women to approach and forgetting about the trial in the midst of a busy labour suite.

In the experimental group, midwives sought consent from women on admission to the labour suite; this is clearly an emotional time at which to seek consent. However, as this trial sought to include only women

Table 7 | Length of labour (hours) by number of admissions before labour. Values are mean (SD) unless stated otherwise

	Experimental		Control	
	Before (n=1029)	After (n=892)	Before (n=1291)	After (n=1279)
Admission to delivery				
Previous admissions:				
0	7.72 (5.09)	9.61 (6.02)	7.30 (5.01)	7.81 (5.43)
1	8.50 (5.81)	8.50 (5.42)	8.57 (5.07)	8.38 (5.30)
2	8.46 (4.83)	11.52 (23.77)	9.92 (4.84)	8.55 (5.36)
3	13.00 (14.55)	9.57 (3.95)	8.11 (5.07)	10.46 (6.61)
4	0	11.82 (11.65)	4.45 (2.99)	12.24 (3.83)
5	0	0	0	0
6	0	0	0	12.90*
Missing data	109	51	98	77
Duration of active labour				
Previous admissions:				
0	9.74 (5.10)	11.31 (5.67)	9.19 (4.88)	9.50 (5.14)
1	10.37 (5.77)	10.47 (5.69)	9.93 (5.06)	9.31 (4.97)
2	9.67 (5.69)	10.10 (4.73)	11.46 (4.75)	10.32 (6.12)
3	9.34 (6.20)	11.67 (5.25)	10.79 (5.45)	11.06 (5.00)
4	0	6.15 (2.7)	10.76 (4.48)	14.61 (2.23)
5	0	0	0	0
6	0	0	0	12.90*
Missing data	145	69	112	98

*One woman only.

Table 8 | Maternal outcomes. Values are numbers (percentages) unless stated otherwise

Outcomes	Experimental		Control		Difference	P value
	Before (n=1029)	After (n=892)	Before (n=1291)	After (n=1279)		
Mode of delivery						
Spontaneous vertex delivery	709 (68.9)	526 (58.9)	810 (63)	785 (61.3)	−3.2 (−15.1 to 8.7)	0.6
Breech	3 (0.2)	0	0	0	NA	NA
Instrumental	205 (19.9)	241 (27.0)	319 (25)	323 (25.2)	NA	NA
Elective caesarean section	4 (0.3)	0	0	3	NA	NA
Emergency caesarean section	106 (10.3)	123 (13.7)	162 (12.5)	165 (12.9)	0.0 (−4.3 to 4.3)	1.0
Missing data	2	2	0	3	NA	NA
Complications						
Any complication	422 (41)	439 (49.2)	571 (44.2)	596 (46.6)	3.9 (−9.4 to 17.2)	0.5
Failure to progress—first stage	70 (6.8)	42 (4.7)	55 (4.3)	59 (4.6)	−3.4 (−15.3 to 8.6)	0.5
Failure to progress—second stage	91(8.8)	142 (15.9)	84 (6.5)	119 (9.3)	15.2 (−4.5 to 34.9)	0.1
Mal position/presentation	11 (1.1)	9 (1.0)	10 (0.8)	16 (1.2)	NA	NA
Intrapartum haemorrhage	10 (1.0)	5 (0.5)	6 (0.5)	7 (0.5)	NA	NA
Postpartum haemorrhage	12 (1.2)	10 (1.1)	16 (1.2)	20 (1.5)	NA	NA
Failed forceps	4 (0.4)	9 (1.0)	1 (0.1)	3 (0.2)	NA	NA
Shoulder dystocia	4 (0.4)	5 (0.5)	13 (1.0)	7 (0.5)	NA	NA
Maternal pyrexia	2 (0.2)	3 (0.3)	12 (0.9)	10 (0.7)	NA	NA
Raised blood pressure	5 (0.5)	4 (0.4)	5 (0.4)	6 (0.4)	NA	NA
Retained placenta	11 (1.1)	16 (1.7)	26 (2.0)	14 (1.0)	NA	NA
Third/fourth degree tear	8 (0.8)	7 (0.7)	10 (0.8)	8 (0.6)	NA	NA

NA=not applicable.

with a normal healthy pregnancy, those women who were particularly vulnerable due to identifiable medical or obstetric risk factors for mother or baby were excluded. Midwives may have deemed it inappropriate to approach women who presented in advanced labour (this has been reported in other intrapartum studies[42]). A systematic bias in the experimental group towards recruiting women admitted in early labour would have resulted in a longer time period between the first labour assessment and delivery in that group. However, we found no significant difference between the groups in this respect, which suggests that no systematic selection occurred in favour of women in early labour in the experimental group.

Our aim was that the trial would have minimal impact in the control units, so no member of staff was given access to the algorithm and no information about the trial was introduced to labour suite midwives. Although we could not recruit women in the control group in the same way as in the experimental group, we used the same trial entry criteria. We maximised the use of anonymised data after the protocol change, to minimise the potential for Hawthorne effects and reduce selection bias.

The admission of women in labour is part of routine midwifery practice, and midwives in both groups probably used the same or similar criteria for diagnosis of labour (we developed the algorithm in consultation with midwives). However, the structuring of these cues in a linear decision rule comprised the intervention tested in this trial. Studies of decision support suggest that it is the consistency of decision support tools, not

Table 9 | Neonatal indicators and outcomes. Values are numbers (percentages) unless stated otherwise

Indicator/outcome	Experimental		Control		Difference	P value
	Before (n=1029)	After (n=892)	Before (n=1291)	After (n=1279)		
In labour:						
Fetal distress	152 (14.7)	166 (18.6)	245 (19.0)	242 (18.9)	2.4 (−6.6 to 11.3)	0.6
Meconium stained liquor	152 (14.8)	133 (14.9)	213 (16.5)	211 (16.6)	−0.5 (−7.2 to 6.3)	0.9
Mean (SD) Apgar:						
At 1 minute	9.52 (10.2)	8.84 (6.9)	8.97 (7.24)	9.21 (8.85)	0.00 (−0.17 to 0.15)	0.9
At 5 minutes	9.25 (0.70)	9.27 (0.79)	9.10 (0.74)	9.14 (0.69)	−0.08 (−0.27 to 0.11)	0.4
Apgar <7 at 5 minutes*	7 (0.6)	9 (1.0)	18 (1.3)	13 (1.0)	–	–
Resuscitation	130 (14.0)	106 (12.7)	151 (12.0)	145 (11.6)	−0.9 (−6.4 to 4.7)	0.7
Missing data	101	58	29	29		
Admitted to neonatal unit	38 (3.6)	29 (3.2)	56 (4.3)	60 (4.6)	−0.4 (−2.6 to 1.8)	0.7
Unplanned out of hospital birth*	6 (0.5)	11 (1.2)	9 (0.6)	11 (0.8)	–	–

*Numbers too small for inferential statistical analysis.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Up to 30% of women admitted to labour wards in the UK may not be in active labour

Women admitted to labour wards in the latent phase of labour are more likely to receive medical intervention than are those admitted in active labour

Previous studies have indicated that the introduction of explicit criteria for diagnosis of labour may reduce oxytocin use

WHAT THIS STUDY ADDS

The introduction of an algorithm to assist with the diagnosis of labour did not reduce oxytocin use

Use of an algorithm for the diagnosis of labour increased the number of times women were admitted and subsequently discharged from hospital before finally being admitted for delivery

Increased rates of intervention in women admitted to labour suites early cannot be fully explained by failure of clinicians to distinguish between the latent and active phases of labour

the provision of new knowledge, that makes them effective.[51][52] However, the reluctance of healthcare professionals to use decision support has been widely reported in other studies.[35][36][53][54] For example, a study of a decision support tool that reduced the rate of false positive diagnosis of acute ischaemic heart disease from 71% to 0% found that the subsequent use of the tool by clinicians was only 2.8%.[55] Several possible reasons have been suggested—in particular, that decision support mediates against individuality of care and that it undermines the skills of the practitioner.[56-58] Use of decision support tools has also been suggested to undermine the clinical credibility of practitioners. Arkes et al found that the diagnostic ability of doctors who used decision support was rated (by students) as lower than that of those who used clinical judgment alone.[59] We assessed the acceptability of the algorithm to midwives during the feasibility study, in which midwives reported willingness to use the algorithm. In the cluster randomised trial, the rate of consent of midwives to use the algorithm varied between units from 57% to 100%. In most (although not all) units, this consent rate reflected the success or otherwise of subsequent data collection. Although an algorithm was completed for each woman, and this gives an indication of compliance with the protocol, midwives could have disregarded its recommendation in deciding whether to admit or discharge women. Studies of how nurses use computerised decision support tools indicate that such tools are often completed after the nurse has made a decision about the care that a patient should receive,[60-63] and this may have contributed to the finding of no difference in the primary outcome. We found evidence that using the algorithm did alter the midwives' judgments, as women in the experimental group were significantly more likely to be discharged after their first labour assessment than were women in the control group. However, these women quickly returned to the hospital, creating a "revolving door" effect. This implies that the observation from other studies of higher rates of intervention in women admitted to labour suites early cannot be fully explained by a failure of clinicians to distinguish between the latent and active phases of labour.

Recommendations and future directions

Admission of women who are not in active labour is a considerable problem leading to higher levels of medical intervention than for those admitted in active labour. Maternity service guidelines advocate advising women to remain at home or to return home until labour is established, but this may be an over-simplistic approach that does not meet the needs of women in early labour. We designed the algorithm to support one aspect of the process of the management of early labour (the diagnosis). The fact that this has not translated into a change in clinical outcomes probably reflects the complexity of management decisions for women in labour, which are influenced by factors such as how a woman is coping with pain and the level of social support available. Studies of women's experience of early labour have found that women in their first pregnancy report feeling unprepared for the latent phase of labour and that their experience is characterised by pain and anxiety.[4][64] Women seek reassurance from hospital admission; although some receive this reassurance, others report feeling that their needs (in particular for pain relief) were not met. Our findings suggest that although the algorithm has the potential to reduce admissions of women not in active labour, merely sending these women home did not produce a clinical benefit. Indeed, it may have contributed to negative experiences for these women. Analysis of postnatal questionnaire data (which will be reported in a separate paper), obtained by use of a discrete choice experiment method, suggested that women had a positive preference for being admitted on initial presentation, as opposed to being discharged home on two or three occasions.

Conclusions

Use of an algorithm for diagnosis of active labour in primiparous women did not result in a reduction in oxytocin use or medical intervention in spontaneous labour. More women in the experimental group were discharged home after their first labour ward assessment. Diagnosis of labour is an important clinical judgment. However, subsequent decisions made about the management of women found to be not yet in labour, or who are in the latent phase, may be the most important and difficult decisions in the care of a woman in labour. Research that includes both women's and clinicians' perspectives about management of early labour is now needed.

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