

## **Screening for breech presentation using universal late pregnancy ultrasonography: A prospective cohort study and cost-effectiveness analysis**

David Wastlund<sup>1\*</sup>, Alexandros A Moraitis<sup>2</sup>, Alison Dacey<sup>2</sup>, Ulla Sovio<sup>2</sup>, Edward CF Wilson<sup>1,3</sup>,  
Gordon CS Smith<sup>2</sup>

<sup>1</sup> Cambridge Centre for Health Services Research, Cambridge Institute of Public Health,  
CB2 0SR Cambridge, UK

(D Wastlund, Research assistant in Health Economics; E Wilson, Senior Research  
Associate in Health Economics)

<sup>2</sup> Department of Obstetrics and Gynaecology, University of Cambridge, NIHR Cambridge  
Comprehensive Biomedical Research Centre, CB2 2SW Cambridge, UK

(AA Moraitis, Clinical Research Fellow; A Dacey, Research Midwife; U Sovio, Senior  
Research Associate in Applied Medical Statistics; GCS Smith, Professor of Obstetrics and  
Gynaecology)

<sup>3</sup> Health Economics Group, Norwich Medical School, University of East Anglia, NR4 7TJ,  
Norwich, UK

\* Jdw78@medschl.cam.ac.uk

### **Correspondence to:**

Prof Gordon CS Smith DSc, Department of Obstetrics and Gynaecology, University of  
Cambridge, The Rosie Hospital, Cambridge, CB2 2SW, UK.

Tel: 01223 763888/763890; Fax: 01223 763889;

E-mail: [gcss2@cam.ac.uk](mailto:gcss2@cam.ac.uk)

Dr Edward CF Wilson PhD, Health Economics Group, Norwich Medical School, University of  
East Anglia, Norwich, NR4 7TJ, UK.

Tel: 01603 593620

E-mail: [ed.wilson@uea.ac.uk](mailto:ed.wilson@uea.ac.uk)

**Key words:** Breech presentation, ultrasound, screening, cost, economic modelling, third-trimester, pregnancy

## **Abstract**

### **Background**

Despite the relative ease with which breech presentation can be identified through ultrasound screening, the assessment of fetal presentation at term is often based on clinical examination only. Due to limitations in this approach, many women present in labour with an undiagnosed breech presentation, with increased risk of fetal morbidity and mortality. This study sought to determine the cost-effectiveness of universal ultrasound scanning for breech presentation near term (36 weeks of gestational age [wkGA]) in nulliparous women.

### **Methods and findings**

The Pregnancy Outcome Prediction (POP) study was a prospective cohort study between January 14, 2008 and July 31, 2012, including 3879 nulliparous women who attended for a research screening ultrasound examination at 36 wkGA. Fetal presentation was assessed and compared for the groups with and without a clinically indicated ultrasound. Where breech presentation was detected, an external cephalic version (ECV) was routinely offered. If the ECV was unsuccessful or not performed, the women were offered either planned caesarean section at 39 weeks or attempted vaginal breech delivery. To compare the likelihood of different mode of deliveries and associated long-term health outcomes for universal ultrasound to current practice, a probabilistic economic simulation model was constructed. Parameter values were obtained from the POP study, and costs were mainly obtained from the English NHS.

179 out of 3879 women (4.6%) were diagnosed with breech presentation at 36 weeks. For most women (96), there had been no prior suspicion of non-cephalic presentation. ECV was attempted for 84 (46.9%) women and was successful in 12 (success rate: 14.3%). Overall, 19 of the 179 women delivered vaginally (10.6%), 110 delivered by elective Caesarean section (61.5%) and 50 delivered by emergency caesarean section (27.9%). There were no women with undiagnosed breech presentation in labour in the entire cohort. On average, 40 scans

were needed per detection of a previously undiagnosed breech presentation. The economic analysis indicated that, compared to current practice, universal late-pregnancy ultrasound would identify around 14,826 otherwise undiagnosed breech presentations across England annually. It would also reduce emergency caesarean section and vaginal breech deliveries by 0.7 and 1.0 percentage points, respectively; around 4,196 and 6,061 deliveries across England annually. Universal ultrasound would also prevent 7.89 neonatal mortalities annually. The strategy would be cost-effective if fetal presentation could be assessed for £19.80 or less per woman. Limitations to this study included that fetal presentation was revealed to all women, and that the health economic analysis may be altered by parity.

**Conclusions** According to our estimates, universal late pregnancy ultrasound in nulliparous women: (1) would virtually eliminate undiagnosed breech presentation, (2) would be expected to reduce fetal mortality in breech presentation, and (3) would be cost-effective if fetal presentation could be assessed for less than £19.8 per woman.

## **Author summary**

### **Why Was This Study Done?**

- Risks of complications at delivery are higher for babies that are in a breech position, but sometimes breech presentation is not discovered until the time of birth.
- Ultrasound screening could be used to detect breech presentation before birth and lower the risk of complications, but would be associated with additional costs.
- It is uncertain if offering ultrasound screening to every pregnancy is cost-effective.

### **What Did the Researchers Do and Find?**

- This study recorded the birth outcomes of pregnancies that were all screened using ultrasound.
- Economic modelling and simulation was used to compare these outcomes with those if ultrasound screening had not been used.
- Modelling demonstrated that ultrasound screening would lower the risk of breech delivery, and as a result reduce emergency Caesarean sections and the baby's risk of death.

### **What Do These Findings Mean?**

- Offering ultrasound screening to every pregnancy would improve the health of mothers and babies nationwide.
- Whether the health improvements are enough to justify the increased cost of ultrasound screening is still uncertain, mainly because the cost of ultrasound screening for presentation alone is unknown.
- If ultrasound screening could be provided sufficiently inexpensive, for example by being used during standard midwife appointments, routinely offering ultrasound screening would be worthwhile.

## Introduction

Undiagnosed breech presentation in labour increases the risk of perinatal morbidity and mortality and represents a challenge for obstetric management. The incidence of breech presentation at term is around 3-4%,<sup>[1-3]</sup> and fewer than 10% of fetuses who are breech at term revert spontaneously to a vertex presentation.<sup>[4]</sup> Although breech presentation is easy to detect through ultrasound screening, many women go into labour with an undetected breech presentation.<sup>[5]</sup> The majority of these women will deliver through emergency Caesarean section, which has high costs and increases risk of morbidity and mortality for both mother and child.

In current practice, fetal presentation is routinely assessed by palpation of the maternal abdomen by a midwife, obstetrician or general practitioner. The sensitivity of abdominal palpation varies between studies (range: 57-70%), and depends on the skill and experience of the practitioner.<sup>[6,7]</sup> There is currently no guidance on what is considered an acceptable false negative rate when screening for breech presentation using abdominal palpation. In contrast, ultrasound examination provides a quick and safe method of accurately identifying fetal presentation.

Effective interventions exist for the care of women who have breech presentation diagnosed near term. The Royal College of Obstetricians and Gynaecologists recommends “that all women with an uncomplicated breech presentation at term should be offered External Cephalic Version (ECV)”.<sup>[2]</sup> The rationale for this is to reduce the incidence of breech presentation at term and avoid the risks of vaginal breech birth or Caesarean section. The success rate of ECV is considered to be approximately 50%,<sup>[2,8,9]</sup> but it differs greatly between nulliparous and parous women (34% and 66% respectively).<sup>[9]</sup> ECV is overall safe with less than 1% risk to the fetus and even smaller risk to the mother;<sup>[10]</sup> despite this a significant number of women decline ECV for various reasons.<sup>[11]</sup> Should ECV be declined, or fail, generally women are offered delivery by planned (elective) caesarean section, as there is level 1 evidence of reduced risk of perinatal death and severe morbidity compared with

attempting vaginal breech birth, and it is also associated with lower costs.[3,12,13] However, some women may still opt for an attempt at vaginal breech birth if they prioritise non-intervention over managing the relatively small absolute risks of a severe adverse event.[1,14]

We sought to assess the cost-effectiveness of universal late pregnancy ultrasound presentation scan for nulliparous women. We used data from the Pregnancy Outcome Prediction (POP) study, a prospective cohort study of >4000 nulliparous women, which included an ultrasound scan at 36 weeks of gestational age (wkGA).[15] Here, we report the outcomes for pregnant nulliparous women with breech presentation in the study, and use these data to perform a cost-effectiveness analysis of universal ultrasound as a screening test for breech presentation.

## Methods

### Study design

The POP study was a prospective cohort study of nulliparous women conducted at the Rosie Hospital, Cambridge (UK) between January 14, 2008 and July 31, 2012, and the study has been described in detail elsewhere.[15-17] Ethical approval for the study was obtained from the Cambridgeshire 2 Research Ethics Committee (reference 07/H0308/163) and all participants provided informed consent in writing. Participation in the POP study involved serial phlebotomy and ultrasound at ~12wkGA, ~20wkGA, ~28wkGA and ~36wkGA.[18] The outcome of pregnancy was obtained by individual review of all case records by research midwives and by linkage to the hospital's electronic databases of ultrasonography, biochemical testing, delivery data and neonatal care data. The research ultrasound at 36wkGA was performed by sonographers and included presentation, biometry, uteroplacental Doppler and placental location. The ultrasound findings were blinded except in cases of breech presentation, low lying placenta or fetal concerns such as newly diagnosed fetal anomaly, and an amniotic fluid index <5cm. This study was not prospectively defined in the POP Study protocol paper[16], but required no further data collection.

If the fetus was in a breech presentation at 36wkGA, women were counselled by a member of the medical team. In line with NICE guidelines, external cephalic version (ECV) was routinely offered unless there was a clinical indication which contra-indicated the procedure, e.g. reduced amniotic fluid volume (AFI <5cm).[18] ECV was performed by one of five obstetric consultants in the unit between 36-38 wkGA, patients were scanned before the procedure to confirm presentation and it was performed with ultrasound assessment; 0.25mg terbutaline SC was given prior to the procedure at the discretion of the clinician. If women refused ECV or the procedure failed, the options of vaginal breech delivery and elective caesarean section were discussed and documented. The local guideline for management of breech presentation, including selection criteria for vaginal breech delivery, was based upon recommendations from

the RCOG.[1] We extracted information about ECV from case records that were individually reviewed by research midwives. Finally, we obtained delivery related information from our hospital electronic database (Protos; iSoft, Banbury, UK).

Fetal outcomes included mode of delivery, birth weight, and gestational age at delivery. We used the UK population reference for birthweight, with the 10<sup>th</sup> and 90<sup>th</sup> percentile cut-offs for small and large for gestational age, respectively; the centiles were adjusted for sex and gestational age.[19] Maternal age was defined as age at recruitment. Smoking status, racial ancestry, alcohol consumption and BMI were taken from data recorded at the booking assessment by the community midwife. Socio-economic status was quantified using the Index of Multiple deprivation (IMD) 2007, which is based on census data from the area in the mother's postcode.[20] Ethical approval for the study was obtained from the Cambridgeshire 2 Research Ethics Committee (reference 07/H0308/163) and all participants provided informed consent in writing.

This study is reported as per the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

### **Statistical analysis**

Data are presented as median (inter-quartile range) or n (%), as appropriate. P-values are reported for the difference between groups calculated using the two-sample Wilcoxon rank-sum (Mann-Whitney) test for continuous variables and the Pearson Chi-square test for categorical variables, with trend tests where appropriate. Comparisons were performed using Stata (version 15.1). Missing values were included in the presentation of patient characteristics and outcomes, but excluded from the economic analysis and estimation of parameters.

### **Economic model and analysis**

To evaluate the cost-effectiveness of routinely offering late pregnancy presentation scan, a decision-tree simulation model was constructed using R (version 3.4.1).[21-24] The time

horizon of the economic analysis was from the ultrasound scan (36wkGA) to infant lifetime, and costs were from the perspective of the English NHS. Costs for modes of delivery were obtained from NHS reference costs;[25] since these do not list a separate cost for vaginal breech delivery, we assumed that the cost ratio between vaginal breech and elective Caesarean section deliveries was the same as in another study (see supporting information, S1 Text).[12]

The population of interest is unselected nulliparous women. The model compares the outcomes at birth for two strategies: 'universal ultrasound' and 'selective ultrasound' (Fig 1). For universal ultrasound we assumed that all breech presentations at the time of scanning would be detected (i.e. assumed 100% sensitivity and specificity for the test). For selective ultrasound, the breech presentation was diagnosed either clinically (by abdominal palpation followed by ultrasound for confirmation) or as an incidental finding during a scan for a different indication. These assumptions were based upon current practice and derived from the POP study.

**Fig 1. Simulation model structure.**

Structure of economic simulation model. 'Universal ultrasound' strategy starts in Model A, and patients with breech presentation enter Model C. 'Selective ultrasound', i.e. no routine ultrasound, starts in Model B, and only those with a detected breech presentation enters Model C. The letter-number codes for each node is equivalent to the codes in Table 1. ELCS = Elective caesarean section; EMCS = Emergency caesarean section.

Compared to a standard antenatal ultrasound where, typically, multiple measurements are made, an ultrasound scan for fetal presentation alone is technically simple. We theorized that such a scan could be provided by an attending midwife in conjunction with a standard antenatal visit in primary care, using basic ultrasound equipment. Since a specific unit cost for a scan for fetal presentation alone is not included in the national schedule of reference costs[25], we estimated the cost of ultrasound to include the midwife's time, the cost of equipment and room. More details are presented in the supporting information, S1 Text. The cost of ECV was obtained from James et al.,[26] and converted to 2017 price level using the

Hospital & Community Health Services (HCHS) index.[27] The probability of ECV uptake and success rate, as well as mode of delivery were obtained from the POP study. All model inputs are presented in Table 1 and S1 Table, and the calculation of cost inputs is shown in supporting information, S1 Text.

**Table 1: Inputs for costs and probabilities for the economic model**

<b>Costs</b>	<b>Costs</b>		<b>Source</b>			
Ultrasound scanning	20.7		Expert opinion *			
ECV	297.4		James et al. (2001)[26] †			
CV delivery	2297.3		NHS Reference costs 2015-16[25] ‡			
Elective caesarean delivery	3438.1		NHS Reference costs 2015-16[25] ‡			
Emergency caesarean delivery	4553.4		NHS Reference costs 2015-16[25] ‡			
VB delivery	3999.7		Expert opinion *			
<b>Probabilities</b>	<b>Alpha</b>	<b>Beta</b>	<b>Mean</b>	<b>Node</b>	<b>Source</b>	
Breech prevalence at ~36wkGA	179	3700	0.046	A1 & B1	POP study	
ECV attempted	84	93	0.475	C1	POP study	
Detection without ultrasound	79	96	0.451	B3	POP study	
Successful ECV	12	72	0.143	C2	POP study	
SRC (ECV not attempted)	21	72	0.226	C3	POP study	
SRB	1	11	0.083	C4	POP study	
SRC (failed ECV)	3	127	0.023	C5	Ben-Meir et al.[28] §	
<b>Mode of delivery</b>	<b>CV</b>	<b>ELCS</b>	<b>EMCS</b>	<b>VB</b>	<b>Node</b>	<b>Source</b>
No breech	2813	141	735	0	A2 & B2	POP study
Cephalic (successful ECV)	8	0	3	0	C8	POP study
Cephalic (spontaneous reversion)	11	1	9	0	C6 & C10	POP study
Breech (ECV not attempted)	0	52	20	0	C7	POP study
Breech (Unsuccessful ECV)	0	54	18	0	C11	POP study
Breech (spontaneous reversion)	0	0	15	11	C9	Leung et al.[5]
Undetected breech	0	0	15	11	B4	Leung et al.[5]

Costs given per unit/episode. For probabilities, Alpha represent case of event and Beta case of no event. Mode of delivery shows input values for Dirichlet distribution. Node refers to the chance nodes in Fig 1.

CV = Cephalic Vaginal; ELCS = Elective caesarean section; EMCS = Emergency caesarean section; IDR = Incidental detection rate; SRB = Spontaneous reversion to breech; SRC = Spontaneous reversion to cephalic; VB = Vaginal breech

\* Details on how this value was estimated is provided as supporting information, S1 Text.

† Cost for ECV (high staff cost), converted to 2017 price level using the Hospital & Community Health Services (HCHS) index.[27]

‡ Weighted average of all complication levels (Total HRG's)

§ Due to the small sample size for these parameters in the POP study, the model used inputs for mode of delivery for undetected breech instead.

The end-state of the decision-tree was the mode of delivery, which was either vaginal, elective Caesarean section (ELCS), or emergency Caesarean section (EMCS). Delivery could be either cephalic or breech. Emergency Caesarean section could be either due to previously undiagnosed breech presentation, or for other reasons. All cases of breech could spontaneously revert to cephalic presentation. However, we assumed the probability of this to be lower if ECV had been attempted and failed.[28] If ECV was successful, a reversion back to breech presentation was possible. It is currently unclear whether the probability of mode of delivery varies depending on whether cephalic presentation is the result of successful ECV or spontaneous reversion,[2,10,29-31] but we assumed that the probabilities differed.

Long-term health outcomes were modelled based upon the mortality risk associated with each mode of delivery (MOD). The risk of neonatal mortality was taken from the RCOG guidelines. For breech presentation, these risks were 0.05% for delivery through ELCS, and 0.20% for vaginal delivery. The risk of neonatal mortality for cephalic presentation with vaginal delivery was 0.10%.[1] There were no randomized clinical trials that allowed us to compare the outcomes of ELCS vs. vaginal delivery for uncomplicated pregnancies with cephalic presentation, however, most observational studies found no significant difference in neonatal mortality and serious morbidity between the two modes.[32-34] For this reason, we assumed the mortality risk for cephalic vaginal and ELCS deliveries to be identical. We also assumed that emergency Caesarean section (EMCS) would have the same mortality rate as ELCS, both for cephalic and breech deliveries. Studies have found that the mode of delivery for breech presentation affects the risk of serious neonatal morbidity in the short term, but not in the long term.[1,3,35] For this reason, we focused the economic analysis on the effect from mortality only. The average lifetime QALYs per member of the UK population was estimated using data on quality of life from Euroqol, weighted by longevity indexes from ONS.[36,37] Using the annual discount rate of 3.5% as recommended by NICE, the net present value for the average lifetime QALYs at birth was 24.3.[38]

The model was probabilistic, capturing how uncertainty in the input parameters affected the outputs by allowing each parameter to vary according to its distribution. Binary and multivariable outcomes were modelled using the beta and the Dirichlet distributions, respectively.[39] Probabilities of events were calculated from the POP study and presented in Table 1. On top of the probabilistic sensitivity analysis, the sensitivity of individual parameters was also explored through one-way sensitivity analyses modifying probabilities by +/- 1 percentage point, and costs by +/- £10, to see which parameters had the greatest impact on cost-effectiveness estimates.

Total costs depended on the distribution of mode of delivery, the number of expected mortalities, and the cost of ultrasound scanning and ECV. Nationwide costs for each screening strategy were calculated for 585,489 deliveries, i.e. the number of births in England 2016-17, assuming 92% occur after 36wkGA.[15,40] Model parameters were sampled from their respective distributions in a Probabilistic Sensitivity Analysis (PSA) of 100,000 simulations for each strategy. To determine cost-effectiveness, we used two different willingness-to-pay thresholds, £20,000 and £30,000.[38] A copy of the model code is available from the corresponding author (EW) upon request.

## Results

Recruitment to the POP study cohort is shown in Fig 2, and has been previously described.[17] Information about presentation at the 36-week scan was available for 3879 women who delivered at the Rosie Hospital, Cambridge, UK; 179 of these had a breech presentation.

### Figure 2: Patient recruitment.

Schedule of patient recruitment in the POP study, shown by fetal presentation.

We compared maternal and fetal characteristics of the 179 women with breech presentation at 36 weeks to the women with a cephalic presentation (Table 2). Women diagnosed with breech presentation were on average a year older than women with a cephalic presentation, but other maternal characteristics did not differ. The babies of women diagnosed breech were smaller and born earlier but their birth weight centile and the proportions of SGA or LGA were not markedly different. There were no differences in maternal BMI between the groups. As expected, women with breech presentation were more likely to deliver by elective or emergency Caesarean section.

**Table 2: Characteristics and delivery outcomes in the POP study by presentation at 36 weeks.**

<b>Characteristics</b>	<b>Breech (N=179)</b>	<b>Cephalic (N=3,700)</b>	<b>P-value</b>
<b>Maternal</b>			
Age (years)	31 (28 - 34)	30 (27 - 33)	0.002
Age stopped FTE (years)	21 (18 - 23)	21 (18 - 23)	0.19
Missing	5 (3%)	105 (3%)	
Racial ancestry			
White European	172 (96%)	3437 (93%)	0.38
Missing	0 (0%)	66 (2%)	
Alcohol consumption	7 (4%)	172 (5%)	0.65
Missing	0 (0%)	1 (<0.1%)	
Smoker	4 (2%)	179 (5%)	0.11
BMI, kg/m2	24 (22 - 27)	24 (22 - 27)	0.69
Missing	0 (0%)	1 (<0.1%)	
Deprivation quartile			0.08
1 (lowest)	46 (26%)	899 (24%)	
2	53 (30%)	873 (24%)	
3	39 (22%)	886 (24%)	
4 (highest)	33 (18%)	892 (24%)	
Missing	8 (4%)	150 (4%)	
<b>Fetal or neonatal</b>			
Female sex	96 (54%)	1841 (50%)	0.31
Missing	0 (0%)	1 (<0.1%)	
Birth weight (grams)	3310 (2995 – 3560)	3445 (3145 – 3750)	<0.001
Gestational age (weeks)	39.1 (38.7 – 39.7)	40.4 (39.4 – 41.3)	<0.001
Birth weight centile	49 (25 – 70)	44 (24 – 66)	0.22
Birth weight centile category			0.32
SGA	12 (7%)	332 (9%)	
AGA	158 (88%)	3199 (86%)	
LGA	9 (5%)	168 (5%)	
Missing	0 (0%)	1 (<0.1%)	
<b>Mode of delivery</b>			<0.001
Spontaneous vaginal cephalic	11 (6.1%)	1885 (50.9%)	
Instrumental vaginal cephalic	8 (4.5%)	928 (25.1%)	
Elective caesarean section	110 (61.5%)	141 (3.8%)	
Emergency caesarean section	50 (27.9%)	735 (19.9%)	
Missing	0 (0%)	11 (0.3%)	

Statistics are presented as n (%) for binary outcomes, and median (inter-quartile range) for continuous variables. The "Missing" category was not included in statistical tests. For variables without a "Missing" category, data were 100% complete. P-values are reported for the difference between groups using the two-sample Wilcoxon rank-sum test for continuous variables and the Pearson Chi-square test for categorical variables, with trend test as appropriate (i.e. for deprivation quartile and birth weight centile category).

FTE= full time education; BMI= body mass index; SGA, AGA and LGA denotes small, average and large for gestational age, respectively.

Breech presentation was suspected before the 36wkGA scan for 79 (44.1%) of the women with breech presentation through abdominal palpation by the midwife or doctor; out of these, 27 had a clinically indicated scan between 32-36 weeks in which the presentation was reported. For 96 women, the breech presentation was unsuspected before the 36-week scan. Information on suspected breech position was missing for 4 women. There were no differences in BMI between the 79 women with suspected breech and the 96 women misdiagnosed as cephalic prior to the scan (median BMI was 24 in both groups, Wilcoxon rank sum test  $p=0.31$ ).

Mode of delivery by external cephalic version (ECV) status is shown in Table 3. ECV was performed for 84 women, declined by 45 women, and unsuitable for 23; contraindications included low AFI at screening (18 women), uterine abnormalities (2), and other reasons (3). For 25 women, an ECV was never performed despite consent; 17 babies turned spontaneously, 6 had reduced AFI on the day of the ECV, and 2 went into labour before ECV. When performed, ECV was successful for 12 women; in one case, the baby later reverted to breech presentation before delivery. Information on ECV uptake was missing for 2 women. Fetal presentation and ECV status in the structure of the economic model is shown in supporting information, S1 Fig.

**Table 3: Mode of delivery by presentation and response to ECV for POP study participants with breech presentation at 36-week scan (n = 179).**

<b>ECV status</b>	<b>Vaginal</b>	<b>ELCS</b>	<b>EMCS</b>	<b>Total</b>
ECV successful	8	1	3	12
ECV unsuccessful	0	54	18	72
ECV not offered *	1	17	5	23
ECV discussed but declined	1	32	12	45
ECV accepted but not performed †	9	5	11	25
Missing	0	1	1	2
<b>Total</b>	<b>19</b>	<b>110</b>	<b>50</b>	<b>179</b>

ELCS = Elective caesarean section; EMCS = Emergency caesarean section

\* 18 women were contraindicated due to low AFI at screening, 2 for uterine abnormalities, and 3 for other reasons

† 17 babies turned spontaneously, 6 had reduced AFI on the day of the ECV, and 2 went into labour before ECV

The results from the economic analysis are presented in Table 4. On average, universal ultrasound resulted in an absolute decrease in breech deliveries by 0.39%. It also led to fewer vaginal breech deliveries (absolute decrease by 1.04%), and overall EMCS deliveries (0.72%) than selective ultrasound, but increased overall deliveries through ELCS (1.51%). Resulting from the more favourable distribution of mode of delivery, the average risk of mortality fell by 0.0013%. On average, 40 women had to be scanned to identify one previously unsuspected breech presentation (95% Credibility Interval (CrI): 33 to 49); across England, this would mean that 14,826 (95% CrI: 12,048 – 17,883) unidentified breech presentations could be avoided annually.

**Table 4: Simulated cost and mode of delivery distribution for universal ultrasound and no ultrasound**

	<b>Universal ultrasound</b>	<b>Selective ultrasound</b>	<b>Difference (per patient)</b>	<b>Difference (Total population)</b>
<b>Total cost</b>	2956.59	2949.30	7.29	4,268,004
<b>Screening cost</b>	20.70	0.43	20.27	11,867,159
<b>ECV cost</b>	6.52	2.94	3.57	2,093,048
<b>Delivery cost</b>	2927.78	2944.31	-16.53	-9,679,396
<b>Mortality cost</b>	1.59	1.62	-0.02	-12,806
<b>Vaginal cephalic</b>	0.6850	0.6826	0.0024	1,399
<b>ELCS cephalic</b>	0.0442	0.0441	0.0001	84
<b>EMCS cephalic</b>	0.2321	0.2305	0.0016	918
<b>Vaginal breech</b>	0.0007	0.0110	-0.0104	-6,061
<b>ELCS breech</b>	0.0273	0.0123	0.0150	8,774
<b>EMCS breech</b>	0.0107	0.0194	-0.0087	-5,115
<b>Total mortality</b>	0.000982	0.000995	-0.000013	-7.89
<b>Total QALY</b>	24.27615	24.27582	0.000327	191.73

Costs (£) are presented per patient, except in column for 'Total population' (n = 585,489).

CV = Cephalic vaginal; ECV = External cephalic version; ELCS = Elective caesarean section; EMCS = Emergency caesarean section; QALY = Quality-adjusted life years; VB = Vaginal breech.

The expected per person cost of universal ultrasound was £2,957 (95% Credibility Interval (CrI): £2,922 - £2,991), compared to £2,949 (95% CrI: £2,915 - £2,984) from selective ultrasound, a cost increase of £7.29 (95% CrI: 2.41 – 11.61). Across England, this means that universal ultrasound would cost £4.27M more annually than current practice. The increase stems from higher costs of ultrasound scan (£20.3 per person) and ECV (£3.6 per person), but is partly offset by the lower delivery costs (-£16.5 per person). The distribution of

differences in costs between the two strategies is shown as supporting information, S2 Fig. The simulation shows that universal ultrasound would on average increase the number of total ELCS deliveries by 8,858 (95% CrI: 7,662 – 10,068), but decrease the number of EMCS and vaginal breech deliveries by 4,196 (95% CrI: 2,779 – 5,603) and 6,061 (95% CrI: 6,617 – 8,670) per year, respectively.

The long-term health outcomes are presented in Table 4. Nationwide, universal ultrasound would be expected to lower mortality by 7.89 cases annually (95% CrI: 3.71, 12.7). After discounting, this means that universal ultrasound would be expected to yield 192 QALYs annually (95% CrI: 90, 308). The cost-effectiveness of universal ultrasound depends on the value assigned to these QALYs. The incremental cost-effectiveness ratio was £23,611 (95% CrI: 8,184, 44,851), which is of borderline cost-effectiveness (given NICE's willingness to pay of £20,000 to £30,000).[38] The number needed to scan per prevented mortality was 74,204 (95% CrI: 46,124 – 157,642).

One-way sensitivity analysis showed that the probability parameter with the greatest impact upon the cost-effectiveness of universal ultrasound was the prevalence of breech: increasing this parameter by 1 percentage point was associated with a relative reduction of costs for universal ultrasound by £3.07. The results were less sensitive to the ECV success rate, an increase by 1 percentage point led to a relative reduction in the cost of universal ultrasound by £0.12. The most important cost parameter was the unit cost of ultrasound scan, an increase in this parameter by £10 led to a relative increase for universal ultrasound by £9.79 (see supporting information, S3 Fig). Keeping all other parameters equal, universal ultrasound would be cost-effective if ultrasound scanning could be provided for less than £19.80 or £23.10 per mother, for a willingness-to-pay threshold of £20,000 or £30,000, respectively. For universal ultrasound to be cost-saving, scans would need to cost less than £12.90 per mother.

## Discussion

In a prospective cohort study of >3,800 women having first pregnancies, a presentation scan at ~36wkGA identified the 4.6% of women who had a fetus presenting by the breech and for more than half of these, breech presentation had not previously been clinically suspected. The majority of these women were ultimately delivered by planned Caesarean section, some experienced labour before their scheduled date and were delivered by emergency Caesarean section, and a small proportion had a cephalic vaginal delivery following either spontaneous or external cephalic version. No woman in the cohort had a vaginal breech delivery, or experienced an intrapartum Caesarean for undiagnosed breech. The low uptake of vaginal breech birth is likely to reflect the fact that this is a nulliparous population and it is generally accepted that the risks associated with vaginal breech delivery are lower in women who have had a previous normal birth.

Our economic analysis suggest that a universal late pregnancy presentation scan would decrease the number of fetal mortalities associated with breech presentation, and that this is of borderline cost-effectiveness, costing an estimated £23,611 per QALY gained. The key driver of cost-effectiveness is the cost of the scan itself. In the absence of a specific national unit cost, we have identified the maximum cost at which it would be cost-effective. This is £19.80 per scan to yield an ICER of £20,000 per QALY, and £23.10 at £30,000. These unit costs may be possible if assessment of presentation could be performed as part of a routine antenatal visit. Portable ultrasound systems adequate for presentation scans are available at low cost, and a presentation scan is technically quite simple, so the required level of skill could be acquired by a large cadre of midwives. This would result in a small fraction of the costs associated with a trained ultra-sonographer performing a scan in a dedicated space using a high specification machine. If universal ultrasound could be provided for less than £12.90 per scan, the policy would also be cost-saving.

Our sensitivity analysis shows that the unit cost of ultrasound scans and the prevalence of breech presentation were by far the biggest determinants of the cost and cost-effectiveness

of universal ultrasound. The detection rate with abdominal palpation (i.e. for selective ultrasound) is the most important parameter aside from these. By contrast, the costs, attempt and success rates for external cephalic version (ECV) have modest impact upon the choice of scanning strategy. It appears that the main short-term cost benefit from late-pregnancy screening lies in the possibility of scheduling elective caesarean sections when breech presentation is detected, rather than turning the baby into a cephalic position.

This analysis may have underestimated the health benefits of universal late pregnancy ultrasound. In the absence of suitable data on long-term outcomes by mode of delivery and fetal presentation, we made the simplifying assumption that mortality rates were equal for elective and emergency caesarean sections. Relaxing this assumption would likely favour universal ultrasound, as this strategy would reduce emergency Caesarean sections and these are associated with higher risks of adverse outcomes than elective Caesarean sections;[41-44] on top of health benefits, this may also reduce long-term NHS costs. It is also possible that an emergency Caesarean section for a known breech presentation is less expensive and has better health outcomes than one where breech is detected intrapartum, although lack of separate data for these two scenarios prevented us from pursuing this analysis further.

Our analysis shows that universal late pregnancy ultrasound screening would increase total number of Caesarean sections. Evidence suggests that caesarean delivery may have long-term consequences on the health of the child (increased risk of asthma and obesity), the mother (reduced risk of pelvic organ prolapse and increased risk of subfertility) and future pregnancies (increased risk of placenta previa and stillbirth).[45,46] There is no evidence that these are related to the type of the Caesarean section (elective vs emergency).[45,46] Our economic modelling has not been able to capture these complex effects due to the model's endpoints, and the focus on the current pregnancy only. However, accounting for these effects, it seems plausible that universal late pregnancy ultrasound would be more favourable for mothers than children or future pregnancies.

Our results are also driven by vaginal delivery yielding worse long-term health outcomes than elective caesarean section (ELCS) for breech presentation.[1] However, even though the rate of vaginal breech birth declined after the Term Breech Study, in many cases the outcomes are not inferior to that of ELCS, and the RCOG guidelines states that vaginal breech delivery may be attempted following careful selection and counselling.[1,3,47] It is hard to assess how an increase in vaginal breech delivery would affect the cost-effectiveness of universal ultrasound; whilst decreased mortality risk from vaginal breech delivery would decrease the importance of knowing the fetal presentation, universal screening would facilitate selection for attempted vaginal breech delivery.

One limitation of this study is that fetal presentation was revealed to all women in the POP study. Consequently, this study cannot say what would have happened without routine screening. However, we felt that it was appropriate to reveal the presentation at the time of the 36wkGA scan as there is level 1 evidence that planned caesarean delivery reduces the risk of perinatal morbidity and mortality in the context of breech presentation at term.[44] Another weakness was that the study was being undertaken in a single centre only, and that the sample size was too small to avoid substantial parameter uncertainty for rare events. Moreover, less than half of all breech presentations in the POP study were detected by abdominal palpation. It is unclear whether the detection rates were affected by midwives knowing that the women were part of the POP study and hence would receive an ultrasound scan at 36wkGA.

The prevalence of breech presentation in this study (4.6%) appears higher than the 3-4% that is often reported in literature.[1] However, this study is unique in that it reports the prevalence at the time of ultrasound scanning, ~36wkGA. Taking into account the number of spontaneous reversions to cephalic, and that some cases of successful ECV may have turned spontaneously without intervention, our finding is consistent with the literature. The ECV success rate in the POP study was considerably lower than reported elsewhere in the literature; it was even lower than the 32% success rate which has been reported as the

threshold level for when ECV is preferred to no intervention at all.[48] This might partly reflect the participants in the POP study; they were older and more likely to be obese than in many previous studies, and the cohort consisted of nulliparous women, who have higher rates of ECV failure than parous women.[9,49,50] It is also possible that the real world ECV success rate is lower than in the literature due to publication bias. However, sensitivity analysis indicates that the impact from an increased ECV success rate would be modest (an increase in ECV success rate by 10 percentage points lowers the incremental cost of universal ultrasound by £0.91 per patient).

The findings from this study cannot easily be transferred to another health system due to the differences in healthcare costs and antenatal screening routines. Some countries, e.g. France and Germany, already offer a third trimester routine ultrasound scan. However, these scans are offered prior to 36 weeks' gestational age and, as many preterm breech presentations revert spontaneously, it would have limited predictive value for breech at term.[51] Whether screening for breech presentation in lower income settings is likely to be cost effective largely depends on the coverage of the health-care system: whilst screening may be relatively more costly, the benefits from avoiding undiagnosed breech presentation may also be relatively larger.

Whether the findings of this study could be extrapolated beyond nulliparous women is hard to assess. The absence of comparable data on screening sensitivity without universal ultrasound for parous women is an important limitation. The risks associated with breech birth also differ between nulliparous and parous women.[52,53] Compared to nulliparous women, parous women have higher success rates for ECV, but also higher risk of spontaneous reversion to breech after 36wkGA.[9,28] Also, the risks associated with vaginal breech delivery are lower in women who have had a previous vaginal birth.[30]

Breech presentation is not the only complication that could be detected through late-pregnancy ultrasound screening. The same ultrasound session could also be used to screen

for other indicators of fetal health such as biometry and signs of growth restriction. Whether also scanning for other complications could increase the benefits from universal ultrasound has been and currently is subject to research.[54,55] Exploring the consequences from such joint screening strategies goes beyond the scope of this paper but has important implications for policy-makers and should therefore be subject to further research.

## **Conclusion**

This study shows that implementation of universal late pregnancy ultrasound to assess fetal presentation would virtually eliminate undiagnosed intrapartum breech presentation in nulliparous women. If this procedure could be implemented into routine care, for example, by midwives conducting a routine 36wkGA appointment and using a portable ultrasound system, it is likely to be cost-effective. Such a programme would be expected to reduce the consequences to the child of undiagnosed breech presentation; including morbidity and mortality.

## **Supporting information**

**S1 Text. Cost input estimation.**

**S1 Table. Input costs and probabilities for the economic model, detailed**

**S1 Fig. Fetal presentation and ECV status in the POP breech study**

**S2 Fig. Probabilistic Sensitivity Analysis (PSA) of cost differences between universal ultrasound and selective ultrasound.**

**S3 Fig. One-way sensitivity analysis of the difference in costs between universal ultrasound and selective ultrasound.**

**S1 STROBE Checklist.**

## References

1. Impey LWM, Murphy D, Griffiths M, Penna LK on behalf of the Royal College of Obstetricians and Gynaecologists. Management of Breech Presentation. *BJOG: an international journal of obstetrics and gynaecology* 2017;124:e151-e77.
2. Impey LWM, Murphy D, Griffiths M, Penna LK on behalf of the Royal College of Obstetricians and Gynaecologists. External Cephalic Version and Reducing the Incidence of Term Breech Presentation. *BJOG: an international journal of obstetrics and gynaecology* 2017;124:e178-e92.
3. Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan R. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. Term Breech Trial Collaborative Group. *Lancet* 2000;356(9239):1375-83.
4. Hunter LA. Vaginal breech birth: can we move beyond the Term Breech Trial? *Journal of midwifery & women's health* 2014;59(3):320-27.
5. Leung WC, Pun TC, Wong WM. Undiagnosed breech revisited. *BJOG: an international journal of obstetrics and gynaecology* 1999;106(7):638-41.
6. Watson WJ, Welter S, Day D. Antepartum identification of breech presentation. *The Journal of reproductive medicine* 2004;49(4):294-6.
7. Nassar N, Roberts CL, Cameron CA, Olive EC. Diagnostic accuracy of clinical examination for detection of non-cephalic presentation in late pregnancy: cross sectional analytic study. *BMJ* 2006;333(7568):578-80.
8. Hofmeyr GJ, Kulier R, West HM. External cephalic version for breech presentation at term. *The Cochrane database of systematic reviews* 2015(4):Cd000083.
9. Beuckens A, Rijnders M, Verburgt-Doeleman GH, Rijninks-van Driel GC, Thorpe J, Hutton EK. An observational study of the success and complications of 2546 external cephalic versions in low-risk pregnant women performed by trained midwives. *BJOG: an international journal of obstetrics and gynaecology* 2016;123(3):415-23.

10. Nassar N, Roberts CL, Barratt A, Bell JC, Olive EC, Peat B. Systematic review of adverse outcomes of external cephalic version and persisting breech presentation at term. *Paediatric and perinatal epidemiology* 2006;20(2):163-71.
11. Rosman AN, Vlemmix F, Fleuren MA, Rijnders ME, Beuckens A, Opmeer BC, et al. Patients' and professionals' barriers and facilitators to external cephalic version for breech presentation at term, a qualitative analysis in the Netherlands. *Midwifery* 2014;30(3):324-30.
12. Palencia R, Gafni A, Hannah ME, Ross S, Willan AR, Hewson S, et al. The costs of planned cesarean versus planned vaginal birth in the Term Breech Trial. *CMAJ* 2006;174(8):1109-13.
13. Henderson J, Petrou S. The economic case for planned cesarean section for breech presentation at term. *CMAJ* 2006;174(8):1118-9.
14. Tunde-Byass MO, Hannah ME. Breech vaginal delivery at or near term. *Seminars in perinatology* 2003;27(1):34-45.
15. Sovio U, White IR, Dacey A, Pasupathy D, Smith GCS. Screening for fetal growth restriction with universal third trimester ultrasonography in nulliparous women in the Pregnancy Outcome Prediction (POP) study: a prospective cohort study. *Lancet* 2015;386(10008):2089-97.
16. Pasupathy D, Dacey A, Cook E, Charnock-Jones DS, White IR, Smith GCS. Study protocol. A prospective cohort study of unselected primiparous women: the pregnancy outcome prediction study. *BMC pregnancy and childbirth* 2008;8:51.
17. Gaccioli F, Lager S, Sovio U, Charnock-Jones S, Smith GCS. The pregnancy outcome prediction (POP) study: Investigating the relationship between serial prenatal ultrasonography, biomarkers, placental phenotype and adverse pregnancy outcomes. *Placenta* 2017;59(Suppl 1):S17-S25.
18. National Institute for Health and Care Excellence. Quality standard: Antenatal care. In: National Institute for Health and Care Excellence, ed., 2012.

19. Freeman JV, Cole TJ, Chinn S, Jones PR, White EM, Preece MA. Cross sectional stature and weight reference curves for the UK, 1990. *Archives of disease in childhood* 1995;73(1):17-24.
20. Noble M, Mclennan D, Wilkinson K, Whitworth A, Exley S, Barnes H, et al. The English indices of deprivation 2007, 2007.
21. R Core Team. R: A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing, 2017.
22. Martin AD, Quinn KM, Park JH. MCMCpack: Markov Chain Monte Carlo in R. *Journal of Statistical Software* 2011;42(9):22.
23. Fan FY. FinCal: Time Value of Money, Time Series Analysis and Computational Finance. R package version 063, 2016.
24. Baio G, Heath A. BCEA: Bayesian Cost Effectiveness Analysis, 2016.
25. Department of Health. NHS Reference Costs 2015-16, 2016.
26. James M, Kevin H, Robin B, Richard J. A decision analytical cost analysis of offering ECV in a UK district general hospital. *BMC Health Services Research* 2001;1(6).
27. Curtis L, Burns A. Unit Costs of Health and Social Care 2017: Personal Social Services Research Unit, 2017.
28. Ben-Meir A, Elram T, Tsafrir A, Elchalal U, Ezra Y. The incidence of spontaneous version after failed external cephalic version. *American journal of obstetrics and gynecology* 2007;196(2):157.e1-3.
29. Rosman AN, Vlemmix F, Ensing S, Opmeer BC, Te Hoven S, Velzel J, et al. Mode of childbirth and neonatal outcome after external cephalic version: A prospective cohort study. *Midwifery* 2016;39:44-8.
30. Krueger S, Simioni J, Griffith LE, Hutton EK. Labour Outcomes After Successful External Cephalic Version Compared With Spontaneous Cephalic Version. *Journal of obstetrics and gynaecology Canada: JOGC = Journal d'obstetrique et gynecologie du Canada: JOGC* 2017.

31. Hants Y, Kabiri D, Elchalal U, Arbel-Alon S, Drukker L, Ezra Y. Induction of labor at term following external cephalic version in nulliparous women is associated with an increased risk of cesarean delivery. *Archives of gynecology and obstetrics* 2015;292(2):313-9.
32. Lavender T, Hofmeyr GJ, Neilson JP, Kingdon C, Gyte GM. Caesarean section for non-medical reasons at term. *The Cochrane database of systematic reviews* 2012(3):Cd004660.
33. National Institute of Health. NIH State-of-the-Science Conference Statement on cesarean delivery on maternal request. *NIH consensus and state-of-the-science statements* 2006;23(1):1-29.
34. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 559: Cesarean delivery on maternal request. *Obstetrics and gynecology* 2013;121(4):904-7.
35. Whyte H, Hannah ME, Saigal S, Hannah WJ, Hewson S, Amankwah K, et al. Outcomes of children at 2 years after planned cesarean birth versus planned vaginal birth for breech presentation at term: the International Randomized Term Breech Trial. *American journal of obstetrics and gynecology* 2004;191(3):864-71.
36. Szende A, Janssen B, Cabasés J. Self-Reported Population Health: An International Perspective based on EQ-5D: Springer Dordrecht Heidelberg New York London, 2014.
37. Office for National Statistics. National Life Tables, United Kingdom, 1980-82 to 2014-16: Office for National Statistics, 2017.
38. National Institute for Health and Clinical Excellence. Guide to the methods of technology appraisal 2013, 2013.
39. Briggs A, Claxton K, Sculpher M. Decision modelling for health economic evaluation. Oxford: Oxford University Press 2006.
40. NHS Digital. NHS Maternity Statistics 2016-17: Summary report: NHS Digital - Health and Social Care Information Centre, 2017.
41. Petrou S, Kim SW, McParland P, Boyle EM. Mode of Delivery and Long-Term Health-Related Quality-of-Life Outcomes: A Prospective Population-Based Study. *Birth* 2017;44(2):110-19.

42. Mackay DF, Wood R, King A, Clark DN, Cooper SA, Smith GCS, et al. Educational outcomes following breech delivery: a record-linkage study of 456947 children. *International journal of epidemiology* 2015;44(1):209-17.
43. Sovio U, Smith GCS. Blinded ultrasonic fetal biometry at 36 weeks and the risk of emergency caesarean delivery: a prospective cohort study of 3,047 low risk nulliparous women. *Ultrasound in obstetrics & gynecology: the official journal of the International Society of Ultrasound in Obstetrics and Gynecology* 2017.
44. Hofmeyr GJ, Hannah M, Lawrie TA. Planned caesarean section for term breech delivery. *The Cochrane database of systematic reviews* 2015(7):Cd000166.
45. Keag OE, Norman JE, Stock SJ. Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. *PLoS medicine* 2018;15(1):e1002494.
46. Moraitis AA, Oliver-Williams C, Wood AM, Fleming M, Pell JP, Smith GCS. Previous caesarean delivery and the risk of unexplained stillbirth: retrospective cohort study and meta-analysis. *BJOG: an international journal of obstetrics and gynaecology* 2015;122(11):1467-74.
47. Pasupathy D, Wood AM, Pell JP, Fleming M, Smith GCS. Time trend in the risk of delivery-related perinatal and neonatal death associated with breech presentation at term. *International journal of epidemiology* 2009;38(2):490-8.
48. Tan JM, Macario A., Carvalho B, Druzin ML, El-Sayed YY. Cost-effectiveness of external cephalic version for term breech position. *BMC pregnancy and childbirth* 2010.
49. Lau TK, Lo KW, Wan D, Rodgers MS. Predictors of successful external cephalic version at term: a prospective study. *BJOG: an international journal of obstetrics and gynaecology* 1997;104(7):798-802.
50. Cho LY, Lau WL, Lo TK, Tang HHT, Leung WC. Predictors of successful outcomes after external cephalic version in singleton term breech pregnancies: A nine-year historical cohort study. *Hong Kong Medical Journal* 2012;18(1):11-19.

51. Witkop CT, Zhang J, Sun W, Troendje J. Natural history of fetal position during pregnancy and risk of nonvertex delivery. *Obstetrics and gynecology* 2008;111(4):875-80.
52. Macharey G, Gissler M, Ulander VM, Rahkonen L, Vaisanen-Tommiska M, Nuutila M, et al. Risk factors associated with adverse perinatal outcome in planned vaginal breech labors at term: a retrospective population-based case-control study. *BMC pregnancy and childbirth* 2017;17(1):93.
53. Parissenti TK, Hebisch G, Sell W, Staedele PE, Viereck V, Fehr MK. Risk factors for emergency caesarean section in planned vaginal breech delivery. *Archives of gynecology and obstetrics* 2017;295(1):51-58.
54. Bricker L, Medley N, Pratt JJ. Routine ultrasound in late pregnancy (after 24 weeks' gestation). *The Cochrane database of systematic reviews* 2015(6):Cd001451.
55. Henrichs J, Verfaillie V, Viester L, Westerneng M, Molevijk B, Franx A, et al. Effectiveness and cost-effectiveness of routine third trimester ultrasound screening for intrauterine growth restriction: study protocol of a nationwide stepped wedge cluster-randomized trial in The Netherlands (The IRIS Study). *BMC pregnancy and childbirth* 2016;16(1):310.