

Erratum II to Biomarker tests to help diagnose preterm labour in women with intact membranes

Produced by	Peninsula Technology Assessment Group (PenTAG) University of Exeter Medical School South Cloisters, St Luke's Campus, Heavitree Road, Exeter, EX1 2LU
Date completed	10/01/2018; Erratum 08/02/2018
Source of funding	This report was commissioned by the NIHR HTA Programme as project number 17/10/01.

Corrections to the executable excel model:

i. There was an error in the executable excel model file in the formulae of column T of Sheet 'Decision Analysis'. This affects the level of maternal QALY losses from neonatal death and the QALYs and ICERs results of scenarios that included maternal QALYs, but has no effect on the base case or other scenario analyses. The effect of correcting the error is to reduce the sensitivity of the results to the inclusion of maternal QALY losses, which had been over-estimated. The terms highlighted in bold should be corrected from the formulae in all rows of column T; for example in cell T3:

```
=QALY_loss_of_mother*(C3*(baseline_Death_risk*(1-RR_Death_ANS≤_7_days))
+G3*(baseline_Death_risk*(1-RR_Death_ANS≤_7_days)))
```

should be revised to:

```
=QALY_loss_of_mother*(C3*(baseline_Death_risk*(1-RR_Death_ANS≤_7_days))
+G3*(baseline_Death_risk__FP≤7d__TPlt37w*(1-RR_Death_ANS__7_days)))
```

Corrections to the Assessment Report

1. Page 159, Table 33, full incremental analysis for the base case at 30 weeks' gestation: text added to last column to clearly identify the dominated test options.

The revised Table 33 is presented below.

2. Page 175-177, section 6.2.6.2 Other scenarios: the ICERs vs. fFN 50ng/ml in the third column (labelled 'With maternal QALYs for 10 years') of Tables 44, 45 and 46, and the Total QALYs, Incremental QALYs and ICERs vs. fFN 50ng/ml and Treat all in Table 47 (scenario including QALY losses for 10 years) and Table 48 (scenario including QALY losses for lifetime) are incorrect.

The corrected pages 175-177 are presented below.

Table 1 Fully incremental analysis of ICERs for women presenting at 30 weeks' gestation at a level 2 hospital

Versus next option in the QALY ranking					
<i>Test</i>	Total costs	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER
<i>Treat-all (test none)</i>	£6,171	22.020	£481	0.002	£233,245
<i>fFN 10 ng/ml^a</i>	£5,690	22.018	£289	0.002	£140,270
<i>fFN 50 ng/ml^a</i>	£5,401	22.016	£346	0.006	£56,033
<i>Actim Partus^a</i>	£5,055	22.010	£160	0.000	Dominated by PartoSure
<i>PartoSure^b</i>	£4,895†	22.010†	-£264	0.003	-£76,870 (Dominates fFN 200 ng/ml)
<i>fFN 200 ng/ml^a</i>	£5,159	22.006	£155	0.014	Dominated by PartoSure
<i>fFN 500 ng/ml^a</i>	£5,004	21.992	-	-	Dominated by PartoSure

Notes: Options have been ranked from most to least effective (in terms of QALYs). ICERs are relative to the next most effective option (i.e. the test in the row immediately below).

Key: ICER, incremental cost effectiveness ratio; fFN, fetal fibronectin; QALY, quality adjusted life years; ^a Bruijn et al.^{45,46}; ^b Hadzi-Lega et al.⁴⁷ for comparison with treat-all, indirect comparison between Bruijn et al. and Hadzi-Lega et al. for comparison with fFN 50 ng/ml (Bruijn et al. was used as the reference study in this case); † Inferred total cost and QALYs for PartoSure obtained by applying relative differences vs Actim Partus found using Hadzi-Lega et al. to Bruijn et al.

Pages 175-177:

ages of 26 and 33 weeks, except for the result that Actim Partus saves £24,534 in healthcare costs per QALY lost among women aged 33 weeks.

Of note, among women aged 26 weeks, presenting at a level 3 hospital (rather than a level 1 or 2 hospital) has the effect of halving the ICERs relative to fFN 50ng/ml. Therefore, this favours treatment-intensive options Treat All and fFN 10ng/ml, which now have an ICER of £61,792 and £46,359, respectively; other options, are favoured by the change, but all now save less than £20,000 per QALY lost relative to fFN 50 ng/ml, except for PartoSure, which saves £26,989 per lost QALY (Table 3).

Table 2 Incremental cost –effectiveness ratios (ICERs) vs fFN 50 ng/ml for women presenting at 30 weeks (level 2 hospital)

Option	Base case	With maternal QALYs for 10 years	Limiting the analysis to delivery (additional cost only)	Limiting the analysis to first year after birth	ANS earlier than 7 days before preterm delivery has partial benefits	Excluding additional neonatal hospital costs of death	Women presenting at level 3 hospital	Applying costs and disutilities of AEs to all AEs
<i>Treat all</i>	£186,757	£175,529	£770	£4,930,444	£41,625	£185,774	£186,757	£174,718
<i>fFN 10 ng/ml^a</i>	£140,270	£131,836	£289	£3,704,229	£24,420	£139,287	£140,270	£131,117
<i>fFN 200 ng/ml^a</i>	£25,213*	£23,697*	-£243	£669,308*	£9,729*	£24,230*	£25,213*	£23,204*
<i>fFN 500 ng/ml^a</i>	£17,013*	£15,990*	-£399	£453,004*	£7,422*	£16,029*	£17,013*	£15,513*
<i>Actim Partus^a</i>	£56,033*	£52,664*	-£347	£1,482,263*	£16,663*	£55,050*	£56,033*	£52,110*
<i>PartoSure^b</i>	£81,925*	£77,000*	-£507	£2,165,244*	£128,511*	£80,942*	£81,925*	£76,395*

Key: ANS, antenatal corticosteroids; AE, adverse event; ICER, incremental cost effectiveness ratio; fFN, fetal fibronectin; QALY, quality adjusted life years; ^a Bruijn et al.^{45,46}; ^b Indirect comparison between Bruijn et al. and Hadzi-Lega et al.⁴⁷ (Bruijn et al. was used as the reference study in this case); * ICER represents the South-West quadrant in cost-effectiveness (i.e. a reduction in both costs and QALYs).

Table 3 Incremental cost –effectiveness ratios (ICERs) vs fFN 50 ng/ml for women presenting at 26 weeks (level 2 hospital)

Option	Base case	With maternal QALYs for 10 years	Limiting the analysis to delivery (additional cost only)	Limiting the analysis to first year after birth	ANS earlier than 7 days before preterm delivery has partial benefits	Excluding additional neonatal hospital costs of death	Women presenting at level 3 hospital	Applying costs and disutilities of AEs to all AEs
<i>Treat all</i>	£129,017	£119,964	£1,604	£3,424,575	£41,178	£127,857	£61,792	£115,081
<i>fFN 10 ng/ml^a</i>	£92,923	£86,402	£578	£2,472,505	£23,977	£91,763	£46,359	£82,280
<i>fFN 200 ng/ml^a</i>	£16,618*	£15,452*	-£488	£459,792*	£8,597*	£15,459*	£8,162*	£12,938*
<i>fFN 500 ng/ml^a</i>	£11,180*	£10,396*	-£803	£316,343*	£6,407*	£10,020*	£5,439*	£7,996*
<i>Actim Partus^a</i>	£35,441*	£32,955*	-£664	£956,295*	£14,661*	£34,282*	£18,393*	£30,044*
<i>PartoSure^b</i>	£53,524*	£49,768*	-£1001	£1,431,265*	£68,956*	£52,364*	£26,989*	£46,476*

Key: ANS, antenatal corticosteroids; AE, adverse event; ICER, incremental cost effectiveness ratio; fFN, fetal fibronectin; QALY, quality adjusted life years; ^a Bruijn et al.^{45,46}, ^b Indirect comparison between Bruijn et al. and Hadzi-Lega et al.⁴⁷ (Bruijn et al. was used as the reference study in this case); * ICER represents the South-West quadrant in cost-effectiveness (i.e. a reduction in both costs and QALYs).

Table 4 Incremental cost –effectiveness ratios (ICERs) vs fFN 50 ng/ml for women presenting at 33 weeks (level 2 hospital)

Option	Base case	With maternal QALYs for 10 years	Limiting the analysis to delivery (additional cost only)	Limiting the analysis to first year after birth	ANS earlier than 7 days before preterm delivery has partial benefits	Excluding additional neonatal hospital costs of death	Women presenting at level 3 hospital	Applying costs and disutilities of AEs to all AEs
<i>Treat all</i>	£323,098	£303,984	£770	£8,522,520	£59,093	£322,132	£323,098	£306,512
<i>fFN 10 ng/ml^a</i>	£242,722	£228,362	£289	£6,402,387	£34,622	£241,755	£242,722	£230,262
<i>fFN 200 ng/ml^a</i>	£43,787*	£41,197*	-£243	£1,154,990*	£14,904*	£42,821*	£43,787*	£41,539*
<i>fFN 500 ng/ml^a</i>	£29,609*	£27,857*	-£399	£780,999*	£11,646*	£28,642*	£29,609*	£28,089*
<i>Actim Partus^a</i>	£97,075*	£91,332*	-£347	£2,560,596*	£24,534*	£96,109*	£97,075*	£92,092*
<i>PartoSure^b</i>	£141,844*	£133,452*	-£507	£3,741,474*	£267,492*	£140,877*	£141,844*	£134,562*

Key: ANS, antenatal corticosteroids; AE, adverse event; ICER, incremental cost effectiveness ratio; fFN, fetal fibronectin; QALY, quality adjusted life years; ^a Bruijn et al.^{45,46}, ^b Indirect comparison between Bruijn et al. and Hadzi-Lega et al.⁴⁷ (Bruijn et al. was used as the reference study in this case); * ICER represents the South-West quadrant in cost-effectiveness (i.e. a reduction in both costs and QALYs).

Table 5 Summary of ICERs for a woman presenting at 30 weeks' gestation (level 2 hospital), including QALY losses to the mother for 10 years in case of infant mortality

Test	Versus treat-all				Versus fFN 50 ng/ml			
	Total costs	Total QALYs	Incremental costs	Incremental QALYs	ICER (per QALY)	Incremental costs	Incremental QALYs	ICER (per QALY)
<i>Actim Partus^a</i>	£5,055	22.012	-£1,116	-0.011	£101,810*	-£346	-0.007	£52,664*
<i>PartoSure^b</i>	£4,895	22.012	-£1,276	-0.011	£116,412*	-£506	-0.007	£77,000*
<i>fFN 10 ng/ml^a</i>	£5,690	22.021	-£481	-0.002	£219,221*	£289	0.002	£131,837
<i>fFN 50 ng/ml^a</i>	£5,401	22.019	-£770	-0.004	£175,529*	£0	0.000	-
<i>fFN 200 ng/ml^a</i>	£5,159	22.008	-£1,012	-0.015	£69,247*	-£242	-0.010	£23,697*
<i>fFN 500 ng/ml^a</i>	£5,004	21.994	-£1,167	-0.029	£39,921*	-£397	-0.025	£15,990*

Key: ICER, incremental cost effectiveness ratio; fFN, fetal fibronectin; QALY, quality adjusted life years; ^a Bruijn et al.^{45, 46}, ^b Hadzi-Lega et al.⁴⁷ for comparison with treat-all, indirect comparison between Bruijn et al. and Hadzi-Lega et al. for comparison with fFN 50 ng/ml (Bruijn et al. was used as the reference study in this case); * ICER represents the South-West quadrant in cost-effectiveness (i.e. a reduction in both costs and QALYs); † Inferred total cost and QALYs for PartoSure obtained by applying relative differences vs Actim Partus found using Hadzi-Lega et al. to Bruijn et al.

Table 6 Summary of ICERs for a woman presenting at 30 weeks' gestation (level 2 hospital), including lifetime QALY losses to the mother in case of infant mortality

Test	Versus treat-all				Versus fFN 50 ng/ml			
	Total costs	Total QALYs	Incremental costs	Incremental QALYs	ICER (per QALY)	Incremental costs	Incremental QALYs	ICER (per QALY)
<i>Actim Partus^a</i>	£5,055	22.016	-£1,116	-0.012	£92,513*	-£346	-0.007	£47,855*
<i>PartoSure^b</i>	£4,895 †	22.016 †	-£1,276	-0.012	£105,781*	-£506	-0.007	£69,968*
<i>fFN 10 ng/ml^a</i>	£5,690	22.026	-£481	-0.002	£199,202*	£289	0.002	£119,797
<i>fFN 50 ng/ml^a</i>	£5,401	22.023	-£770	-0.005	£159,500*	£0	0.000	-
<i>fFN 200 ng/ml^a</i>	£5,159	22.012	-£1,012	-0.016	£62,923*	-£242	-0.011	£21,533*
<i>fFN 500 ng/ml^a</i>	£5,005	21.996	-£1,167	-0.032	£36,275*	-£397	-0.027	£14,529*

Key: ICER, incremental cost effectiveness ratio; fFN, fetal fibronectin; QALY, quality adjusted life years; ^a Bruijn et al.^{45, 46}, ^b Hadzi-Lega et al.⁴⁷ for comparison with treat-all, indirect comparison between Bruijn et al. and Hadzi-Lega et al. for comparison with fFN 50 ng/ml (Bruijn et al. was used as the reference study in this case); * ICER represents the South-West quadrant in cost-effectiveness (i.e. a reduction in both costs and QALYs); † Inferred total cost and QALYs for PartoSure obtained by applying relative differences vs Actim Partus found using Hadzi-Lega et al. to Bruijn et al.