

The mechanical dilator (DILAPAN-S) for inpatient cervical ripening: A UK economic model

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Objective

To evaluate the cost, staff time, and clinical consequences of utilising DILAPAN-S compared to Propess for cervical ripening during inpatient induction of labour (IOL) in the United Kingdom (UK).

Design

- A cost-consequence analysis based on data from a large randomised trial (SOLVE) and the clinical practice of three UK maternity units.
- The IOL pathway was modelled using a Markov-model with a time horizon from admission for IOL to birth. (Figure 1)

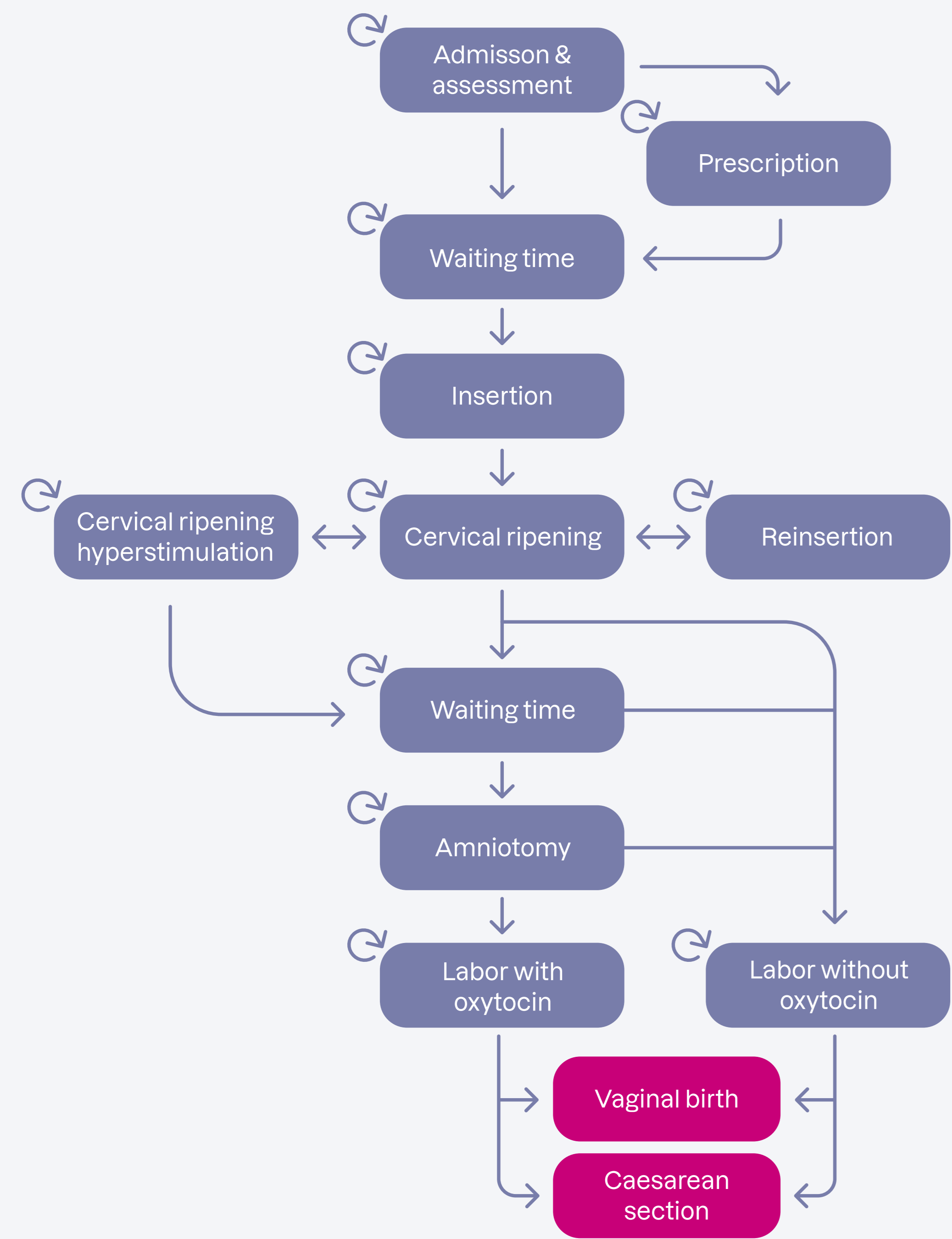


Figure 1. Schematic representation of the Markov model of the inpatient process of IOL until birth.

All women entered the model at the 'Admission & assessment state'. Women receiving Propess required a prescription while women receiving DILAPAN-S were exempt and moved directly to the waiting state for insertion. All women received either Propess or DILAPAN-S until these devices were removed or fell out and, after waiting for staff and resource availability, labour was initiated. Women could receive an amniotomy with or without subsequent oxytocin augmentation for labour. The final states were either vaginal birth or birth via caesarean section. At all intermediate states, women could move to the caesarean section state (not illustrated here for simplification purposes).

Disclaimer

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Method

- A health-economic model was developed comparing IOL utilising two NICE recommended cervical ripening agents (CRAs): DILAPAN-S and Propess.
- Induction-to-delivery care pathways, including staff-time requirements, were modelled on the SOLVE trial (NCT03001661) and clinical experience from three UK maternity units.
- The care pathway included the prescription and insertion of the CRA, cervical ripening, waiting time before labour initiation, and the time from labour to birth.

Table 1. Key clinical safety and efficacy parameters

Input	DILAPAN-S	Propess
Primary caesarean birth nulliparous women, % (SD)	41.6 (9.7)	35.9 (9.4)
Primary caesarean birth, multiparous women, % (SD)	20.6 (7.9)	27.7 (8.8)
Oxytocin augmentation, % (SD)	62.7 (9.5)	39.3 (9.6)
Spontaneous delivery following induction, % (SD)	38.3 (5.7)	39.3 (7.7)
Uterine hyperstimulation with fetal heart-rate changes, % (SD)	0.0 (0.0)	4.3 (4.0)
Any strong opioids during cervical ripening, % (SD)	6.2 (4.7)	17.5 (7.4)
Entonox during cervical ripening, % (SD)	19.0 (1.9)	8.6 (0.9)
Time admission to induction, hours (range)	1.0 (0.6 – 1.6)	0.60 (0.4 – 1.1)
Time admission to amniotomy, hours (range)	44.2 (26.9 – 67.1)	44.6 (23.8 – 72.0)
Time admission to birth, hours (range)	52.9 (35.8 – 78.6)	45.3 (24.7 – 74.6)
Time amniotomy to birth, hours (range)	10.1 (5.9 – 15.2)	9.3 (4.8 – 13.4)
Ripening time, hours (range)	21.2 (16.1 – 24.8)	24.4 (13.9 – 34.7)

All clinical input parameters were taken or calculated from the published SOLVE trial.¹ CRA, cervical ripening agent; SD, standard deviation.

Table 2. Key resource parameters

Input	Value	Source
Continuous monitoring after CRA administration, DILAPAN-S, minutes per 24 hours	20	Consensus from clinical experience
Continuous monitoring after CRA administration, Propess, minutes per 24 hours	160	Consensus from clinical experience
Cost vaginal birth, GBP (SD)	49 (5)	Schroeder et al. 2017 ²
Cost caesarean section, GBP (SD)	1,755 (175)	Schroeder et al. 2017 ²

All input values were rounded to the nearest minute or pound, respectively. CRA, cervical ripening agent; SD, standard deviation. Costs are given in 2020 GBP.

- During cervical ripening, events requiring midwife attention were possible: hyperstimulation, analgesic administration, amniotomy, oxytocin augmentation, and fetal monitoring.
- Cost and clinical inputs were sourced from the SOLVE trial (NCT03001661) and peer-reviewed literature identified from a structured review of PubMed, supplemented by manual searches and a consensus of the clinical authors' experience and hospital protocols. (Table 1 & 2)
- The cohort of hypothetical patients in the model had the same mean characteristics as in the SOLVE trial and were eligible to receive either CRA.
- Model robustness was assessed utilising a probabilistic, multivariable sensitivity analysis with over 500 simulations, reported as median (interquartile range, IQR).

Results

- Compared to Propess, the use of DILAPAN-S was associated with a reduction in staff-time requirements.
- The mean required midwifery and obstetrician times were decreased by 147 and 11 minutes, respectively.
- This was primarily due to reduced monitoring requirements when using DILAPAN-S.
- Moreover, DILAPAN-S was associated with a lower rate of hyperstimulation and need for strong opioid analgetics, which further decreases staff time.
- Introducing DILAPAN-S was found to be cost neutral compared to Propess. (Table 3)
- The sensitivity analysis indicated that the model was robust to changes in the input parameters with 88% of 500 simulations finding that DILAPAN-S would reduce midwifery time; simulation average of -210 minutes (IQR: -324 to -78).

A: Midwife

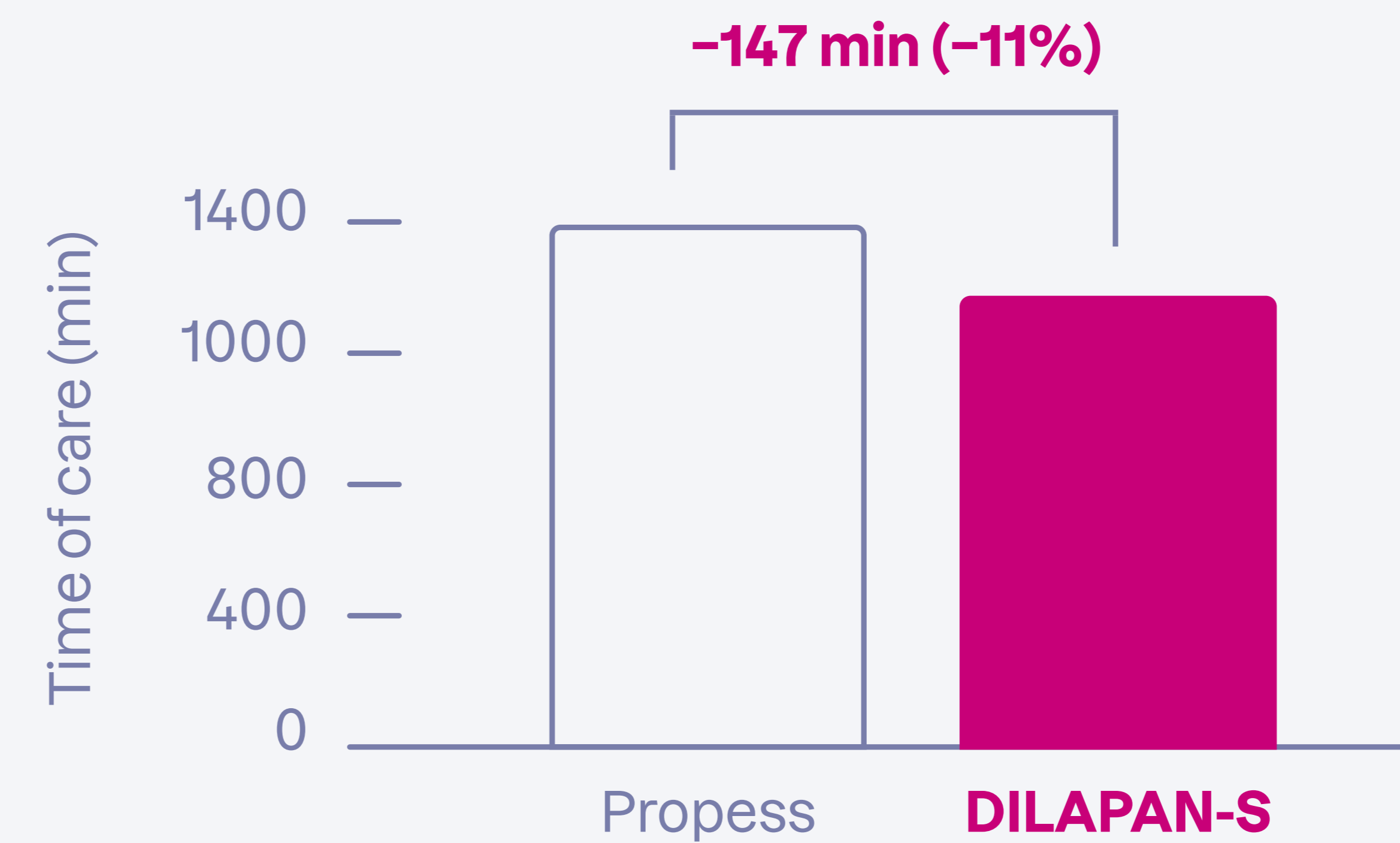


Figure 3. Reduction of required (A) midwife and (B) obstetrician time.

Times only consider care related to differences in the care pathway depending on which CRA was received. (A) Midwife time required. The majority of midwife time saved with DILAPAN-S (211 minutes) was accrued during cervical ripening. In contrast, the DILAPAN-S group experienced fewer spontaneous vaginal deliveries, which increased the length of stay in the maternity unit of this group with the associated resource consumption. (B) Obstetrician time required. This difference in obstetrician time was mostly due to Propess requiring a prescription, whereas DILAPAN-S did not.

Conclusions

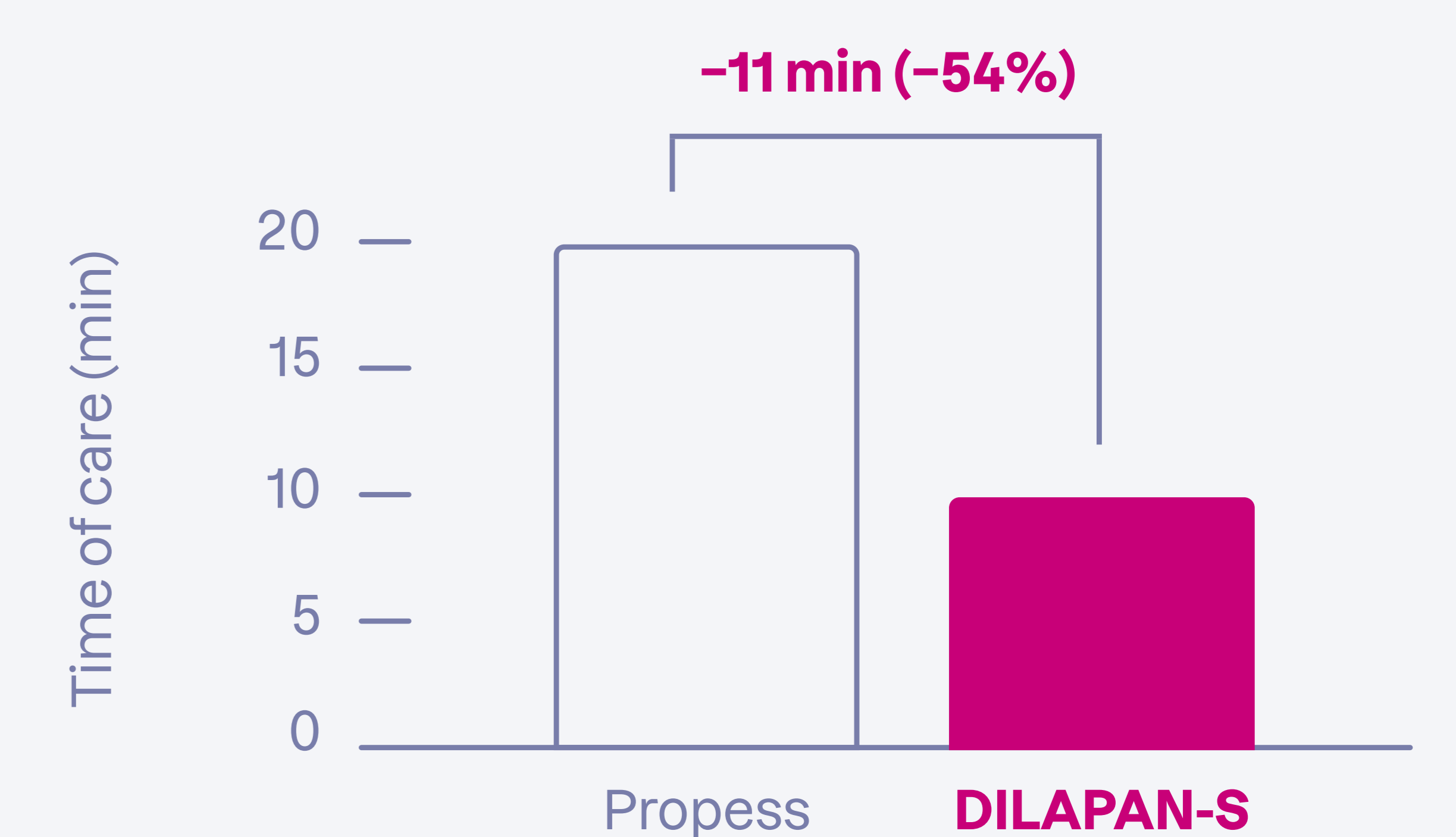
- Adoption of DILAPAN-S is likely to be cost-neutral, therefore adding this CRA to UK practice is not expected to increase hospital spending.
- In addition, the model predicts a reduction in the birth-related staff burden, which could potentially aid in freeing up staff capacity during periods of high demand.

Table 3. Total care cost by ripening agent and phase of birth

	DILAPAN-S	Propess	Difference
Admission	£33	£58	-£25
Ripening*	£1,785	£1,917	-£132
Labour	£1,708	£1,556	+£152
Total	£3,525	£3,531	-£6
Total without waiting times	£2,654	£2,662	-£8

*Waiting time included. All costs are given in 2020 British pounds and rounded to the nearest pound.

B: Obstetrician



References

- Gupta JK, Maher MA, Stubbs MC, Brocklehurst P, Daniels JP, Hardy MP, et al. A randomized trial of synthetic osmotic cervical dilator for induction of labor versus dinoprostone vaginal insert. Am J Obstet Gynecol MFM. 2022;4:1-20.
- Schroeder L, Patel N, Keeler M, Rocca-Ihenacho L, Macfarlane A. The economic costs of intrapartum care in Tower Hamlets: A comparison between the cost of birth in a freestanding midwifery unit and hospital for women at low risk of obstetric complications. Midwifery. 2017;45:28-35.