# Dilapan-S® for cervical ripening in the outpatient setting

## Cost-consequence analysis in the United States of America

### Clinical context

Elective induction of labor (IOL) at 39 weeks may significantly decrease cesarean section rates in comparison to expectant management.[1] Increasing the number of women in the labor and delivery unit for IOL, however, might pose a considerable burden on hospital staff and resources.

### Dilapan-S® for outpatient cervical ripening

Dilapan-S® is indicated for use in cervical ripening prior to IOL. Dilapan-S® may facilitate out-of-hospital (outpatient) ripening because cardiotocography monitoring is not required. In the DILAFOL trial, women report an increase in the ability to sleep, relax, and perform daily activity with Dilapan-S® when compared to the balloon catheter.[2]

### Model methodology

This cost-consequence model assesses the economic and clinical impact of adopting outpatient cervical ripening with Dilapan-S® following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidance.[3] It models the hospital perspective with a time horizon and care provision from admission for IOL to post-delivery discharge. A hypothetical cohort of women indicated for IOL with an unfavorable cervix are assessed. In the hospital, women receive the selected prostaglandin and those who are contraindicated to receive prostaglandins are ripened with the single-balloon catheter. In the comparison, selected low-risk women undergo outpatient ripening with Dilapan-S®. See the associated publication for further details.[4]

### Setting-specific analysis

The reported results are specific to the setting described by the inputs chosen for the model. Results for other settings or using different methods of cervical ripening are likely to vary considerably.

1. Grobman WA, et al. Labor induction versus expectant management in low-risk nulliparous women. N. Engl. J. Med. 379, 513–523 (2018).

2. Saad AF, et al. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am. J. Obstet. Gynecol. 220, 275.e1-275.e9 (2019).

3. Caro JJ, et al. Modeling good research practices - overview: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force-1. Value Health. 5(5):796-803 (2012).

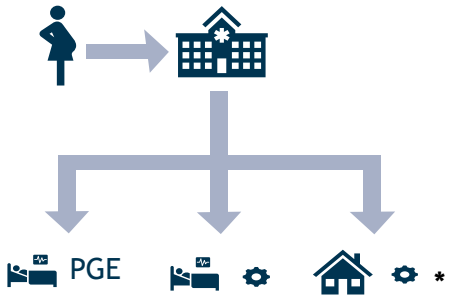
4. Saunders SJ, et al. Out-of-hospital cervical ripening with a synthetic hygroscopic cervical dilator may reduce hospital costs and cesarean sections in the United States—a cost-consequence analysis. Submitted (2021).

# Methodology

The model compares the current standard of care to a potential future scenario. These differ in the distribution of women across different methods of cervical ripening:

- In the hospital using the Vaginal PGE2 insert (inpatient prostaglandin)
- In the hospital using the Balloon catheter (inpatient mechanical)
- Out of the hospital using Dilapan-S® (outpatient mechanical)


### Standard of care

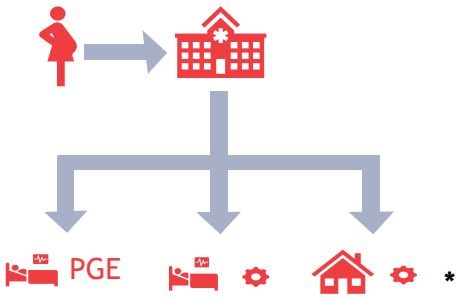



**79.0%** Vaginal PGE2 insert

**21.0%** Balloon catheter

**0.0%** Dilapan-S®

### Future scenario with outpatients




**46.3%** Vaginal PGE2 insert

**12.3%** Balloon catheter

**41.4%** Dilapan-S®

## Cervical ripening method and setting assigned in the model

The use of cervical ripening method and inpatient/outpatient setting is based on the population characteristics. High-risk women are ripened inpatient only. Women with a previous cesarean section and/or are contraindicated to receive prostaglandins are ripened using a mechanical method.

## Model calculations for populations

The model performs calculations using population percentages. An exact population size is not defined because calculations are proportional to any population size.

*** Women for outpatient mechanical ripening have Dilapan-S® inserted in the hospital and are then sent to a non-medical, private location for ripening with instructions when to return to the hospital for removal and delivery.**

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# Model structure

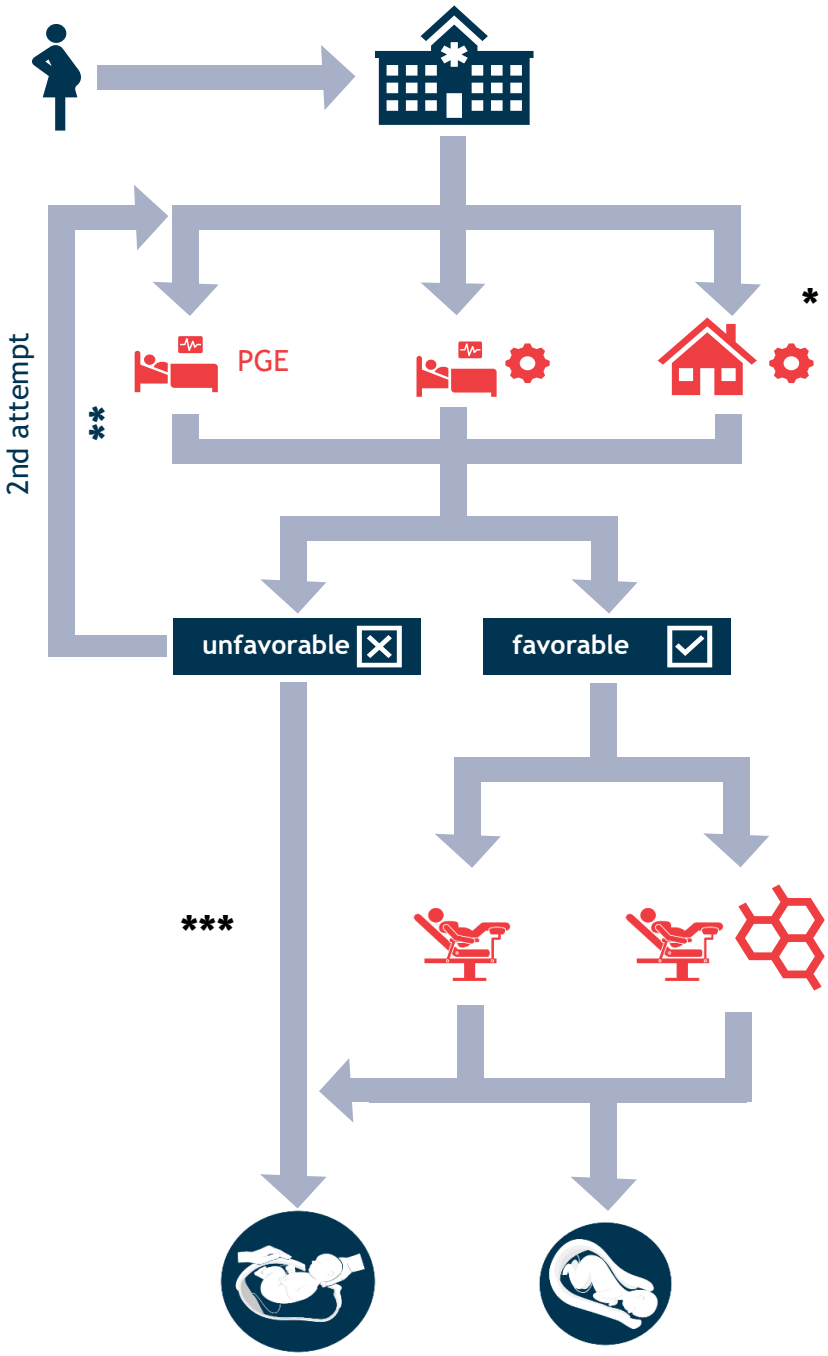
Pregnant woman with unfavorable cervix is indicated for induction of labor

Cervical ripening either:
-Inpatient prostaglandin
-Inpatient mechanical
-Outpatient mechanical

Cervical status
(If unfavorable, woman receives 2nd attempt of cervical ripening)

Spontaneous labor or oxytocin augmented labor

Cesarean section or vaginal birth




* Women for outpatient mechanical ripening have Dilapan-S® inserted in the hospital and are then sent to a non-medical, private location for ripening with instructions when to return to the hospital for removal and delivery, or a second attempt at cervical ripening.

** The same ripening method as in the 1st attempt is used when a 2nd attempt of cervical ripening is required.

*** Oxytocin is not given after a failed 2nd attempt of cervical ripening.

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# Key model parameters - infographic

The model user specified all given values or accepted the model default value (see next page).

## Population information

High-risk pregnancies

18.6 %

Primiparous

31.4 %


Previous cesarean section

12.3 %

Women contraindicated to receive prostaglandins*

21.0 %


## Intervention information


Prostaglandin chosen

Vaginal PGE2 insert**

Low-risk women switched to outpatient cervical ripening ***

50.9 %

* It is assumed that all women with a previous cesarean section are contraindicated to receive prostaglandins. These women are included in this number.

** Women contraindicated to receive prostaglandins are given the balloon catheter (inpatient setting).

*** Dilapan-S® is used (outpatient setting).

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# Key model parameters - table

| Input | Chosen input | Default input | Literature source for the default input |
|---|---|---|---|
| **Population information** | | | |
| High-risk pregnancies | 18.6% | 18.6% | Grobman, WA et al. Labor induction versus expectant management in low-risk nulliparous women. N. Engl. J. Med. 379, 513-523 (2018). |
| Primiparous | 31.4% | 31.4% | Hehir, MP et al. Cesarean delivery in the United States 2005 through 2014: a population-based analysis using the 75,. Am. J. Obstet. Gynecol. 219, 105.e1-105.e11 (2018). |
| Previous cesarean section | 12.3% | 12.3% | Hehir, MP et al. Cesarean delivery in the United States 2005 through 2014: a population-based analysis using the 75,. Am. J. Obstet. Gynecol. 219, 105.e1-105.e11 (2018). |
| Contraindicated to PGE2 insert/gel | 21.0% | 21.0% | Assumption from clinical practice. |
| Prostaglandin chosen* | Vaginal PGE2 insert | NA | None, required user input. |
| Low-risk women switched to outpatient cervical ripening** | 50.9% | 50.9% | Son, SL et al. Outpatient Cervical Ripening: A Cost-Minimization and Threshold Analysis. Am J Perinatol; 37(3):245-251. doi:10.1055/s-0039-1694791 (2020). |
| **Inpatient versus outpatient ripening** | | | |
| Cesarean sections | RR 0.63 | RR 0.63 | Abdelhakim, AM et al. Outpatient versus inpatient balloon catheter insertion for labor induction: A systematic review and meta-analysis of randomized controlled trials. J. Gynecol. Obstet. Hum. Reprod. 101823 (2020) doi:10.1016/j.jogoh.2020.101823. |
| Labor & delivery unit time saved | 5.5 hours | 5.5 hours | Dong, S et al. Inpatient versus outpatient induction of labour: A systematic review and meta-analysis. BMC Pregnancy Childbirth 20, 1-10 (2020). |
| **Differing cesarean section rates** | | | |
| Primiparous (primary) | 25.5% | 25.5% | Hehir, MP et al. Cesarean delivery in the United States 2005 through 2014: a population-based analysis using the 75,. Am. J. Obstet. Gynecol. 219, 105.e1-105.e11 (2018). |
| Multiparous (primary) | 8.1% | 8.1% | Hehir, MP et al. Cesarean delivery in the United States 2005 through 2014: a population-based analysis using the 75,. Am. J. Obstet. Gynecol. 219, 105.e1-105.e11 (2018). |
| VBAC | 13.3% | 13.3% | Osterman, MJK. Recent Trends in Vaginal Birth After Cesarean Delivery: United States, 2016-2018. NCHS Data Brief 1-8 (2020). |
| **Key costs (inflated to 2020 US dollars)** | | | |
| Cesarean section delivery | $18,132 | $18,132 | Vesco, KK et al. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Matern. Child Health J. 24, 30-38 (2020). |
| Vaginal delivery | $12,875 | $12,875 | Vesco, KK et al. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Matern. Child Health J. 24, 30-38 (2020). |
| Labor & delivery unit cost per hour | $133 | $133 | Son, SL et al. Outpatient Cervical Ripening: A Cost-Minimization and Threshold Analysis. Am. J. Perinatol. 37, 245-251 (2020). |
| Purchase cost for Dilapan-S® | $304 | $304 | Medicem Inc. list price,2020 with mean rods from Gupta J. et al. Synthetic osmotic dilators in the induction of labour—An international multicentre observational study. Eur J Obstet Gynecol Reprod Biol. 2018;229:70-75. doi:10.1016/j.ejogrb.2018.08.004 |
| Purchase cost for the balloon catheter | $8 | $8 | Levine, LD. Cervical ripening: Why we do what we do. Semin. Perinatol. 44, (2020). |
| Purchase cost for the 'Vaginal PGE2 insert' | $297 | $297 | Wing, DA & Sheibani, L. Pharmacotherapy options for labor induction. Expert Opin. Pharmacother. 16, 1657-1668 (2015). |

RR - relative risk. NA - not applicable. The model is based on over 80 parameters. The above parameters are selected because they have a higher impact on model outcomes.

* Women contraindicated to receive prostaglandins are given the balloon catheter (inpatient setting).

** Dilapan-S® is used (outpatient setting).

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# Results

## Total cost saving
(per woman from hospital admission for IOL to post-delivery discharge)

**$682 USD**

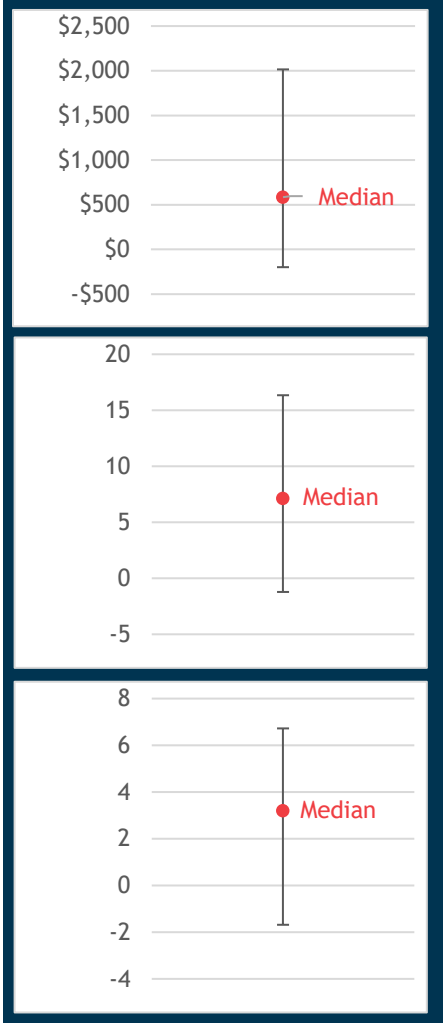
## Change in VBACs per 100 TOLACs

**9.1**

## Cesarean sections prevented per 100 women

**3.8**

## Sensitivity analysis




## Time in labor and delivery per woman from hospital admission for IOL to post-delivery discharge

**-1.5 hrs**

## Hospital stay after delivery per woman from hospital admission for IOL to post-delivery discharge

**-0.9 hrs**

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# Bibliography

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## Model inputs

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**Moulton, L. J.,** Munoz, J. L., Lachiewicz, M., Liu, X. & Goje, O. Surgical site infection after cesarean delivery: incidence and risk factors at a US academic institution. J. Matern. Neonatal Med. 31, 1873–1880 (2018).
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**Saunders, SJ, et al.** Out-of-hospital cervical ripening with a synthetic hygroscopic cervical dilator may reduce hospital costs and cesarean sections in the United States—a cost-consequence analysis. Submitted

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