

**Disclosure:** SJS is an employee and RS is the owner of Coreva Scientific GmbH & Co KG, which received consultancy fees for performing, analyzing, and communicating the work presented here. TW is an employee of Medicem Inc, the US agent and initial importer of Dilapan-S® and company funding this research. AFS is an expert consultant and part of the advisory board for the sponsor.

# The cost consequences of adopting outpatient cervical ripening using a synthetic hygroscopic cervical dilator for low-risk women indicated for induction of labor.

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## Learning Objectives

- Offering women that require labor induction with an unfavorable cervix and who have a low-risk profile the opportunity to have cervical ripening outside of the hospital (outpatient) is not only well received by the women but may potentially save up to US\$689 per delivery and 2.4 hours of time in the hospital.
- Reducing childbirth costs and time in the hospital can allow more women to undergo elective induction of labor to decrease the risk of a cesarean section.
- Outpatient cervical ripening could also allow for a decrease in demand on both nursing time and overall hospital labor & delivery (L & D) admission time.

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# PURPOSE

To assess the feasibility (economic and clinical consequences) of adopting an out-of-hospital (outpatient) strategy for low-risk women requiring cervical ripening prior to induction of labor (IOL).

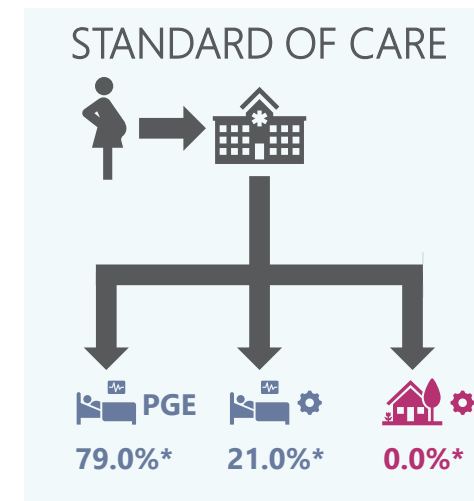
- Elective IOL at 39 weeks may significantly decrease cesarean section rates in comparison to expectant management.<sup>1,2,3</sup>
- Increasing the number of women in the delivery unit for IOL, however, might pose a considerable burden on hospital staff and resources.
- Cervical ripening using a synthetic hygroscopic cervical dilator, indicated for use for cervical ripening prior to IOL and with a safety profile not requiring neonatal monitoring, may facilitate outpatient ripening.
- Following guidance from the International Society for Pharmacoeconomics and Outcomes Research, an economic cost-consequence model from a hospital perspective, with a time horizon from admission for IOL to post-delivery discharge, was developed to compare two scenarios:
  1. Standard of care: cervical ripening is **inpatient only**.
  2. A mix of **inpatient vaginal prostaglandin (PGE)** , **inpatient single-balloon catheter**  and **outpatient synthetic hygroscopic cervical dilator**  for cervical ripening.

## Scenario comparison

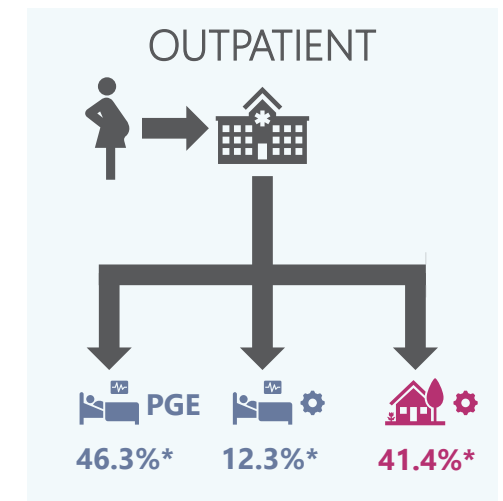
1

vs

2



Cervical ripening is inpatients only (IP-only)



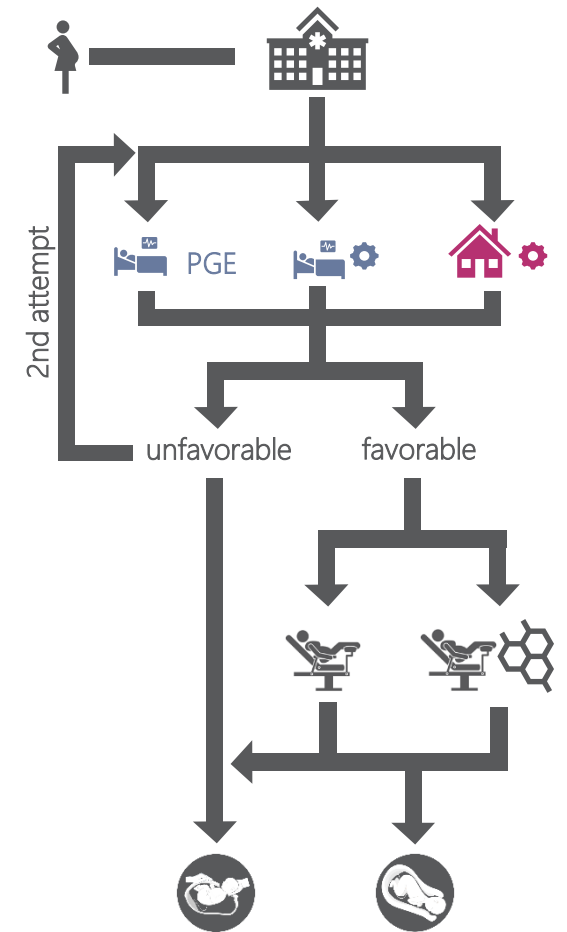
Mix of inpatients and outpatients as expected to occur in practice (OP-select)

# METHODOLOGY I

## MODEL STRUCTURE

- The model uses decision trees to model the induction to delivery care pathway (right).
- Outcomes are reported as the average over all women assessed, comparing **OP-select** to **IP-only** strategies.
- Outcomes can be applied to a population of any size >100 women.
- The robustness of model outcomes were tested using a probabilistic multivariate sensitivity analysis, testing 2,000 sets of feasible parameter input variations.

1. **Pregnant woman** with unfavorable cervix is indicated for induction of labor.
2. **Cervical ripening** either
  - Inpatient vaginal PGE2
  - Inpatient single-balloon catheter.
  - **Outpatient synthetic hygroscopic cervical dilator.**
3. **Cervical status**  
if unfavorable, woman receives a 2<sup>nd</sup> attempt of cervical ripening.
4. **Labor**  
Spontaneous or oxytocin augmented.
5. **Delivery**  
Cesarean section or natural birth.



# METHODOLOGY II

## MODEL INPUTS & POPULATION

- Model inputs were sourced from a structured review of peer-reviewed articles in PubMed.
- Most source articles are from large US databases, randomized controlled trials, or meta-analyses.
- Women categorized as having a high-risk pregnancy were not eligible for outpatient ripening in the **OP-select** scenario.

### PATIENT POPULATION



18.6%<sup>1</sup>

High-risk pregnancies



31.4%<sup>2</sup>

Primiparous



12.3%<sup>2</sup>

Previous cesarean section



21.0%<sup>3</sup>

Contraindicated to receive prostaglandins

<sup>1</sup> [Grobman WA](#), et al. N. Engl. J. Med. 379, 513–523 (2018); <sup>2</sup> [Hehir MP](#), et al. Am J Obstet Gynecol. 219:105.e1-11 (2018); <sup>3</sup> Assumption from clinical practice; <sup>4</sup> [Abdelhakim AM](#) et al. J Gynecol Obstet Hum Reprod. (2020) 2019:101823; <sup>5</sup> [Dong S](#), et al. BMC Pregnancy Childbirth 20, 1–10 (2020); <sup>6</sup> [de Vaan MD](#), et al. Cochrane Database Syst. Rev. doi:10.1002/14651858.cd001233.pub3 (2019); <sup>7</sup> [Saad AE](#), et al. Am. J. Obstet. Gynecol. 220, 275.e1-275.e9 (2019). <sup>8</sup> [Osterman MJK](#) et al. NCHS Data Brief. 359:1–8 (2020). <sup>9</sup> [Maier JT](#), et al. J. Perinat. Med. 46, 299–307 (2018). <sup>10</sup> [Vesco KK](#), et al. Matern. Child Health J. 24, 30–38 (2020); <sup>11</sup> [Son SL](#), et al. Am. J. Perinatol. 37, 245–251 (2020).

### KEY CLINICAL INPUTS

#### Inpatient vs outpatient cervical ripening

Cesarean sections	RR 0.6 [0.5–0.9] <sup>4</sup>
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L&D unit time saved	5.5 hours [2.0–9.0] <sup>5</sup>
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#### Differing cesarean section rates for

Primiparous (primary)	25.5% <sup>2</sup> RR** 0.7 [0.3–1.5] <sup>6,7</sup>
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Multiparous (primary)	8.1% <sup>2</sup> RR** 1.0 [0.3–2.9] <sup>6,7</sup>
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VBAC*	13.3% <sup>8</sup> RR** 1.1 [0.7–1.6] <sup>9</sup>
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### KEY COST INPUTS (2020 US \$)

Cesarean delivery***	\$18,132 <sup>10</sup>
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Vaginal delivery***	\$12,875 <sup>10</sup>
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L&D unit per hour	\$133 <sup>11</sup>
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RR—risk ratio; L&D unit- Labor & delivery unit; VBAC-vaginal birth after previous cesarean  
 \* Reported as vaginal birth rate.  
 \*\* Vaginal PGE2 insert versus SHCD.  
 \*\*\* Cost from admission to discharge

# RESULTS

- Cost savings were up to US\$689 per woman when implementing the **OP-select** strategy.
- Women were predicted to spend 1.48 h less time in the labor and delivery unit and 0.91 h less in the postpartum recovery unit.
- The cesarean section rate was decreased by 3.78 percentage points (23.28% decreased to 19.50%).
- Probabilistic multivariate sensitivity analysis was performed to ascertain the robustness of results.
  - Testing 2,000 feasible scenarios, hospital costs and the cesarean section rate were reduced in 91% of all instances.

## Conclusion

- An outpatient strategy for cervical ripening reduces costs, time spent in hospital, and cesarean sections.
- Enabling low-risk women to undergo cervical ripening out of the hospital may allow nurses to focus more attention on those women requiring additional care.



\$ 689

Total cost saving per woman



9.1

More VBACs per 100 TOLACs



3.8

Fewer cesarean sections per 100 women



2.4 h

Shorter hospital stay per woman