

**ACRONYMS** SHCD—synthetic hygroscopic cervical dilator; IOL—induction of labor; PGE—prostaglandin; SOC—standard of care; VBAC—vaginal birth after previous cesarean; TOLAC—trial of labor after cesarean; L&D—labor and delivery.

## INTRODUCTION & AIM

- Managing COVID-19 has put pressure on hospital budgets and resources. Shifting low-risk procedures to the outpatient setting has the potential to relieve some resource use. The SHCD (Dilapan-S<sup>®</sup>) is indicated for use in cervical ripening prior to IOL. The SHCD may facilitate out-of-hospital (outpatient) cervical ripening because cardiotocography monitoring is not required.
- We assessed the **clinical and economic** impact of adopting **outpatient cervical ripening** with a SHCD for low-risk women undergoing (elective) IOL at term; how might this help in the current **COVID-19 pandemic**?

## METHOD – A COST-CONSEQUENCE MODEL (Developed following ISPOR guidelines<sup>1</sup>)

- The model uses decision trees for the care pathway and these settings:
  - Economic perspective—an average **US-hospital payer**.
  - Time horizon—from admission for IOL to post-delivery discharge.
- As the **SOC**, all women were ripened as **inpatients** and received:
  - Vaginal PGE2 (Cervidil<sup>®</sup>) unless contraindicated.
  - The single-balloon catheter (Foley) if PGE is contraindicated.
- As the **outpatient comparison**, selected low-risk women underwent cervical ripening in the outpatient setting.
  - Women in the outpatient setting received the SHCD.
  - All other women received the SOC as inpatients.

1. KEY CLINICAL INPUTS	
<b>Inpatient vs outpatient cervical ripening</b>	
Cesarean sections	RR 0.6 [0.5–0.9] <sup>2</sup>
L&D unit time saved	5.5 hours [2.0–9.0] <sup>3</sup>
<b>Differing cesarean section rates for</b>	
Primiparous (primary)	25.5% <sup>4</sup> RR§ 0.7 [0.3–1.5] <sup>5,6</sup>
Multiparous (primary)	8.1% <sup>4</sup> RR§ 1.0 [0.3–2.9] <sup>5,6</sup>
VBAC*	13.3% <sup>7</sup> RR§ 1.1 [0.7–1.6] <sup>8</sup>

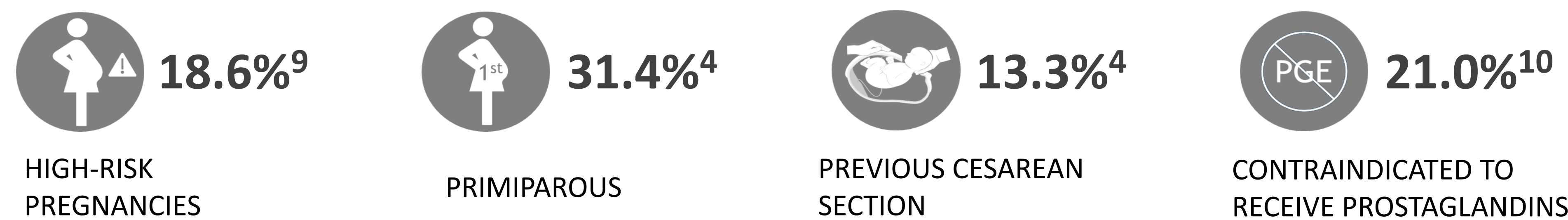
\* Reported as vaginal birth rate. RR—risk ratio. §Vaginal PGE2 insert versus SHCD.

## STRUCTURED LITERATURE REVIEW TO SOURCE MODEL INPUTS

- Cost and clinical input data were sourced from a structured literature review of PubMed. Most source articles are from large US databases, randomized controlled trials, or meta-analyses. Key model inputs are presented in Tables 1 & 2.

## PATIENT POPULATION

- In both SOC and outpatient scenarios, a hypothetical cohort of women indicated for IOL with an unfavorable cervix were assessed. Mean characteristics of the population were:



## CALCULATIONS AND MODEL ROBUSTNESS

- The model performs calculations on the “average” woman using population percentages. All results reported are the mean per delivery.
- A **probabilistic multivariate sensitivity** analysis was performed, testing 2,000 feasible scenarios (random parameter settings).

## MODEL STRUCTURE

1. Pregnant woman with unfavorable cervix is indicated for induction of labor at term

2. Cervical ripening either:

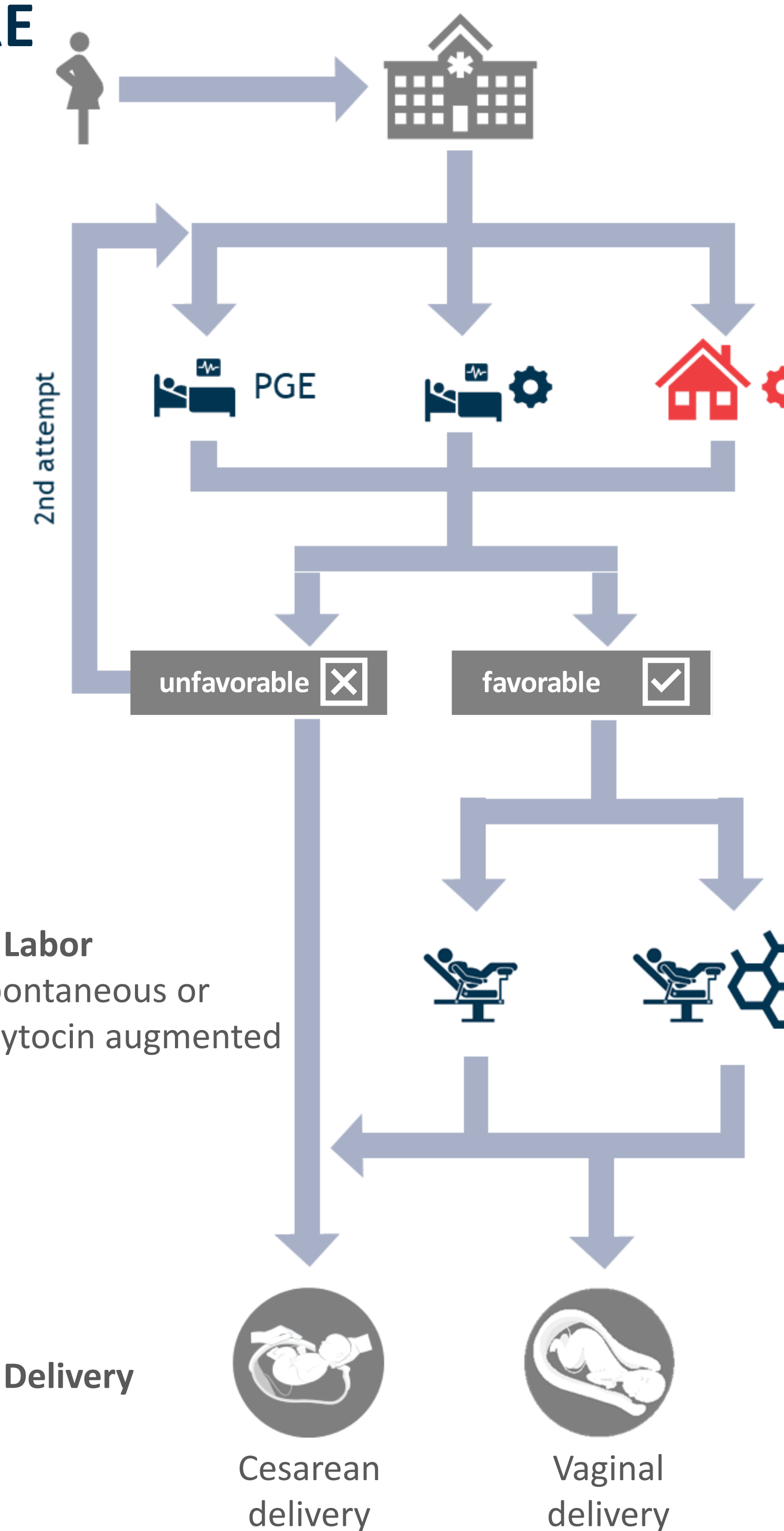
- Inpatient vaginal PGE2
- Inpatient Foley
- Outpatient SHCD

3. Cervical status (if unfavorable, woman receives 2<sup>nd</sup> attempt of cervical ripening)

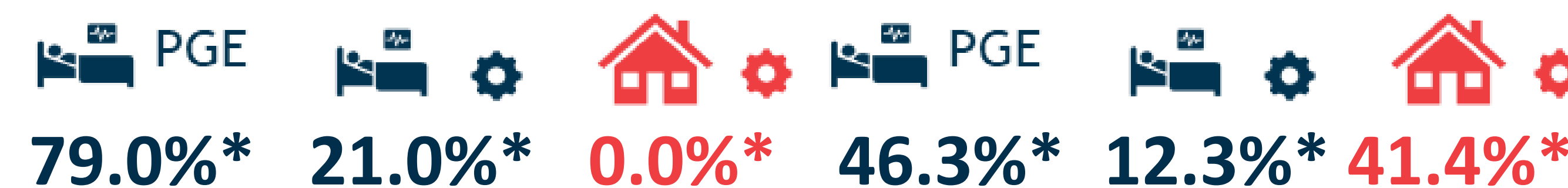
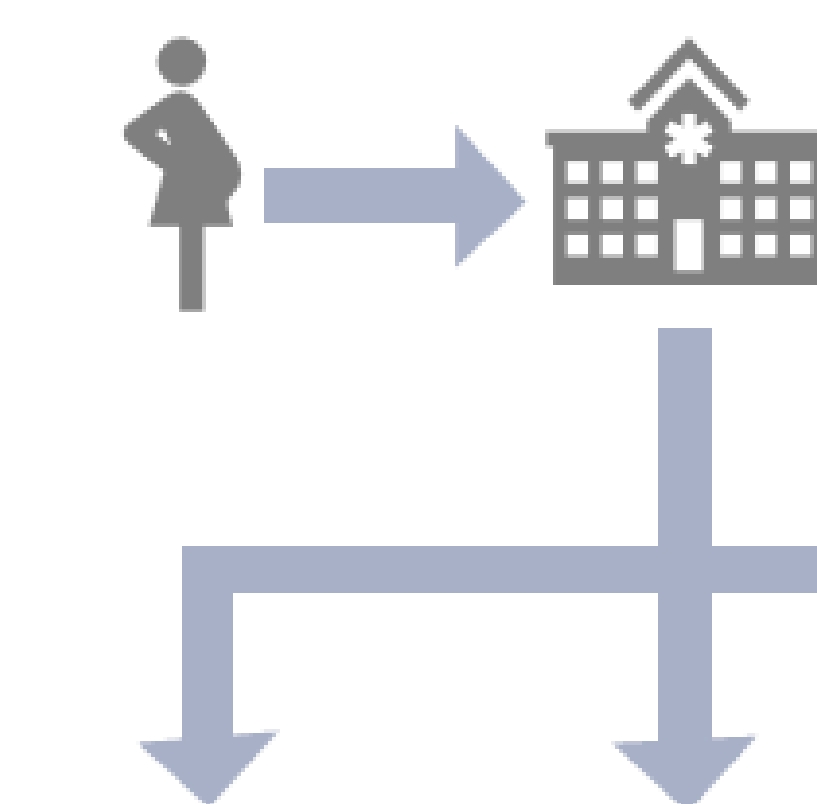
4. Labor

Spontaneous or oxytocin augmented

\* Cost from admission to discharge



## SOC SCENARIO

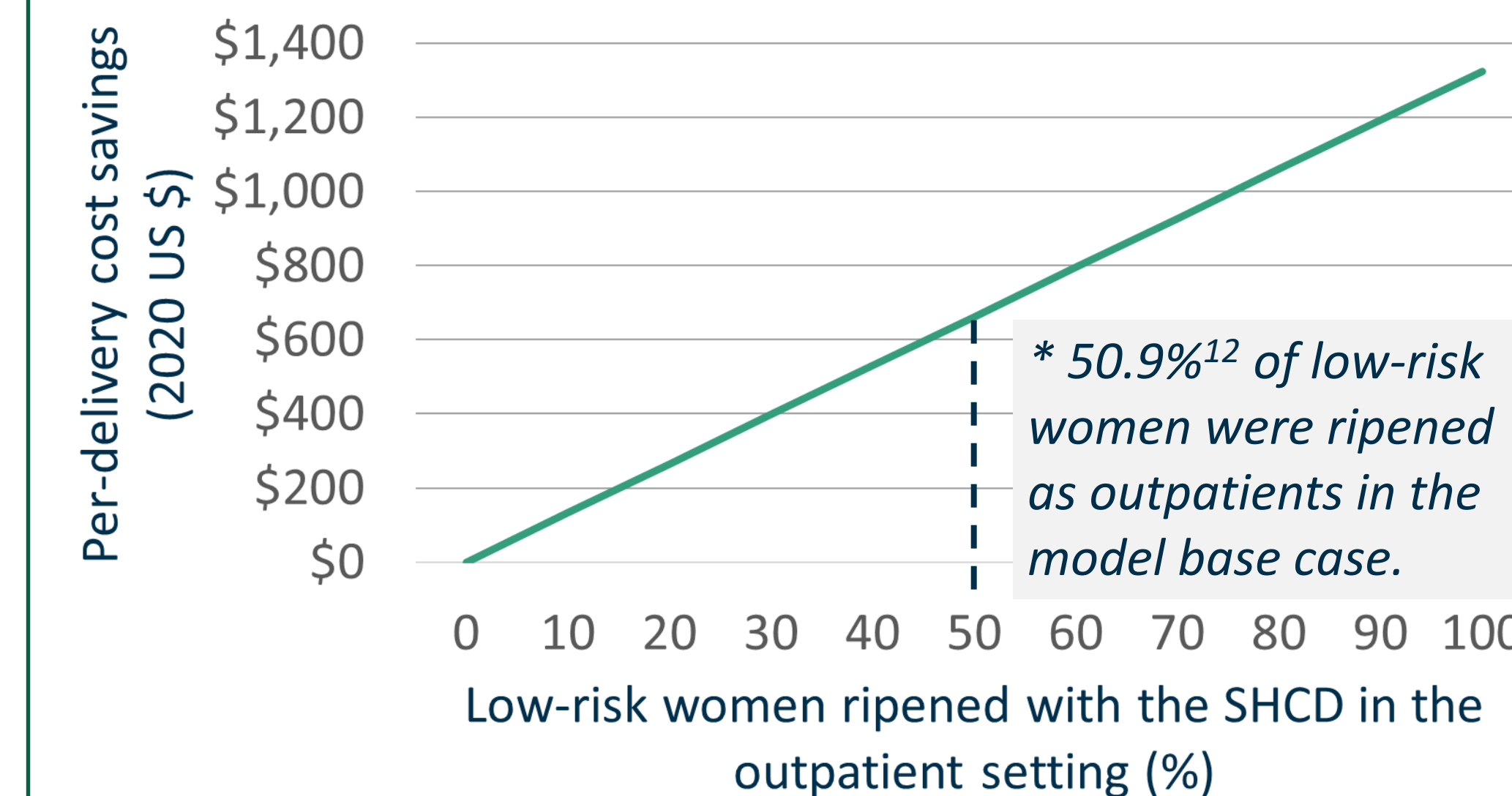
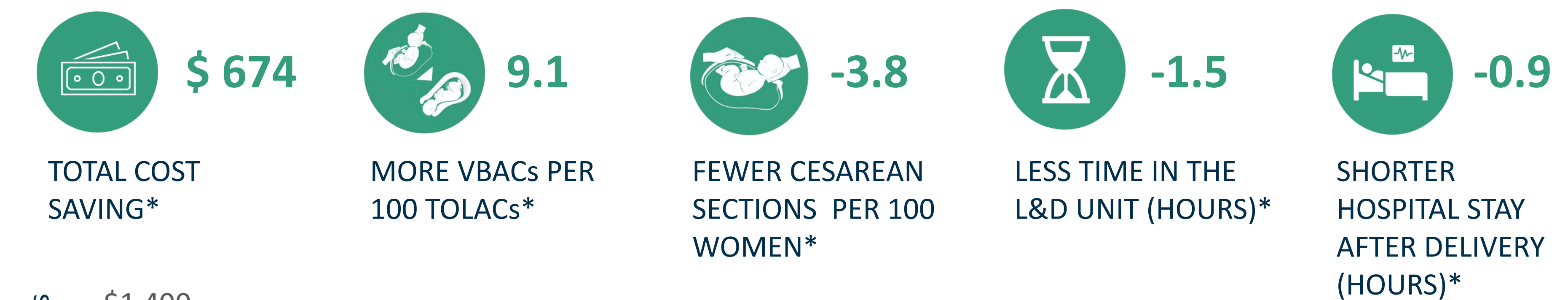


\* Calculated by the decision trees in the model from the population characteristics.

## RESULTS (Results were updated since abstract submission)

When comparing outpatient ripening for low-risk women with the inpatient-only strategy:

- Women spent 2.39 hours **less time in hospital**. -1.48 hours in the L&D unit and -0.91 hours in the recovery unit.
- Cost savings were US \$674 per woman overall\* and **US \$2,042 per woman switched** to the outpatient setting.
- Cesarean sections were decreased by 3.78 percentage points (23.2% vs 19.5%).



- The model predicts cost **savings from the first woman** ripened out of hospital (left figure).
- Time saved in the L&D unit likely covers the additional expense of the SHCD and longer ripening time.<sup>5,6</sup>
- Testing 2,000 feasible scenarios, costs and the cesarean section rate were reduced in 91% of all instances; VBACs in 96% of instances.

## CONCLUSIONS AND RELEVANCE TO THE COVID-19 PANDEMIC

- Adopting outpatient cervical ripening for low-risk women may **reduce average delivery costs**, even with a small proportion of women for outpatient ripening; this may help to **counteract the financial burden** due to the pandemic.
- Hospitals may begin with **few** women ripened in the outpatient setting and subsequently **expand** their offer as evidenced by results from their own clinical practice, while expecting cost reductions.
- The results further suggest that outpatient ripening reduces hospital stay by several hours. This may also contribute to preventing infection by **reducing physical contacts**, a key issue during the ongoing COVID-19 pandemic.

## REFERENCES

1. Caro JJ, et al. Value Health. 5(5):796-803 (2012); 2. Abdelhakim AM, et al. J. Gynecol. Obstet. Hum. Reprod. 101823 (2020); 3. Dong S, et al. BMC Pregnancy Childbirth 20, 1–10 (2020); 4. Hehir MP, et al. Am J Obstet Gynecol. 219:105.e1-11 (2018); 5. de Vaan MD, et al. Cochrane Database Syst. Rev. doi:10.1002/14651858.cd001233.pub3 (2019); 6. Saad AF, et al. Am. J. Obstet. Gynecol. 220, 275.e1-275.e9 (2019). 7. Osterman MJK, NCHS Data Brief 1–8 (2020). 8. Maier JT, et al. J. Perinat. Med. 46, 299–307 (2018). 9. Grobman WA, et al. N. Engl. J. Med. 379, 513–523 (2018); 10. Assumption from clinical practice; 11. Vesco KK, et al. Matern. Child Health J. 24, 30–38 (2020); 12. Son SL, et al. Am. J. Perinatol. 37, 245–251 (2020).