



# How to counsel patients when the data is not there

Nathan Blue, MD  
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How to counsel patients when the data is not there



No financial disclosures



## How to counsel patients when the data is not there



### Learning Objectives:

- How to be a nice person
- How to be a good listener
- How to be reasonable



## How to counsel patients when the data is not there



### Learning Objectives:

- Review 3 scenario types re: availability of evidence
- Review steps of effective shared decision making
- Identify resources



## How to counsel patients when the data is not there



### Data-Scenario Types™

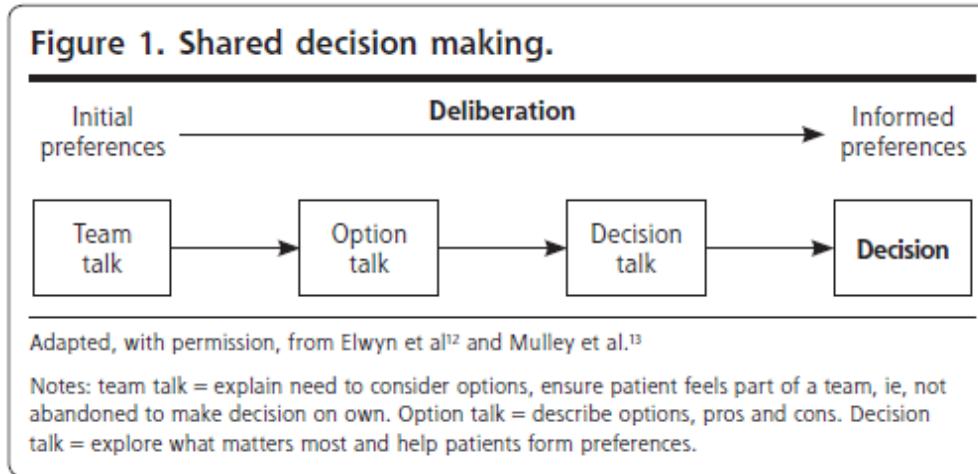
- Data-lacking
- Data-rich
- Data-useless



### Shared Decision Making in Three Steps:

- Introduce choice (*Team talk*)
- Describe options (*Option talk*)
- Explore values, make decisions (*Decision talk*)

**Figure 1. Shared decision making.**



Elwyn G et al, Ann Fam Med 2014



## How to counsel patients when the data is not there



### Data Scenario 1: Data-lacking:

- Scant information or data doesn't apply to your patient
- Guidelines are inadequate



## How to counsel patients when the data is not there



### Data Scenario 1: Data-lacking:

- Opportunity:
  - Management can be guided by patient-centered outcomes
  - Search Pubmed, find cool stuff
- Potential pitfalls:
  - Easy to introduce bias - common sense can be misleading
  - Low quality evidence is *always missing something*
- Helpful resources:
  - Pubmed, Google



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### Example case:

- 27yo G2P1001 at 21w
  - BMI 45
  - Started walking, eating better
  - 8lb weight loss initially, now weight stable but not gaining
  - “Doctor, is that okay?”

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# INSTITUTE OF MEDICINE

**TABLE 1 NEW RECOMMENDATIONS FOR TOTAL AND RATE OF WEIGHT GAIN DURING PREGNANCY, BY PREPREGNANCY BMI**

Prepregnancy BMI	BMI* (kg/m <sup>2</sup> ) (WHO)	Total Weight Gain Range (lbs)	Rates of Weight Gain* 2nd and 3rd Trimester (Mean Range in lbs/wk)
Underweight	<18.5	28–40	1 (1–1.3)
Normal weight	18.5–24.9	25–35	1 (0.8–1)
Overweight	25.0–29.9	15–25	0.6 (0.5–0.7)
Obese (includes all classes)	≥30.0	11–20	0.5 (0.4–0.6)



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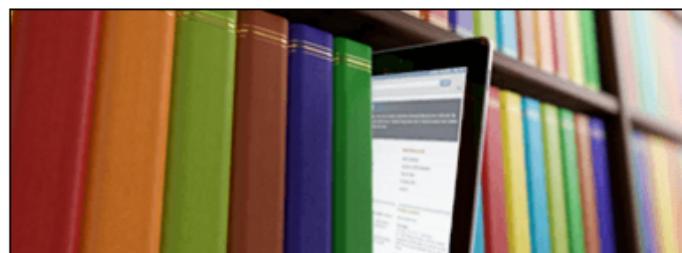
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# Weight Loss in Obese Pregnant Women and Risk for Adverse Perinatal Outcomes

re



*Annick Bogaerts, PhD, Lieveke Ameye, PhD, Evelyne Martens, MSc, and Roland Devlieger, PhD*

**OBJECTIVE:** To examine the association between weight loss in obese pregnant women and relevant maternal and neonatal outcomes.

**METHODS:** All liveborn singleton term (37 weeks of gestation or greater) births in obese women between 2009 and 2011 in Flanders (the northern part of Belgium) were included ( $N=18,053$ ). Outcomes assessed included gestational hypertension, low (2,500 g or less) birth weight, small-for-gestational-age (less than the 10th percentile) neonates, macrosomia (birth weight 4,000 g or greater), large-for-gestational-age (greater than 90th percentile) neonates, emergency caesarean delivery, and admission to a neonatal intensive care unit. Risk for adverse outcomes was calculated by multiple logistic regression analysis for weight change categories (greater weight loss [5 kg or greater], lesser weight loss [between 0 and 5 kg], low gestational weight gain [0 or greater and less than 5 kg], adequate gestational weight gain [5 or greater to 9 kg or less, reference], and excessive gestational weight gain [greater than 9 kg]) in each obesity class (I 30–34.9, II 35–39.9, III 40 or greater) adjusted for parity and maternal and gestational age.

**RESULTS:** In the total population, 854 (4.7%) obese pregnant women reported weight loss. Weight loss and low weight gain were associated with a decreased incidence of gestational hypertension for women with class I obesity (greater weight loss adjusted odds ratio [OR] 0.31, 95% confidence interval [CI] 0.11–0.84; lesser weight loss adjusted OR 0.46 95% CI 0.21–0.99; low gain adjusted OR 0.71 95% CI 0.54–0.93), a reduction in the rate of emergency cesarean delivery, but only in those with class II obesity (greater weight loss adjusted OR 0.24, 95% CI 0.07–0.78; lesser weight loss adjusted OR 0.50, 95% CI 0.26–0.97; low gain adjusted OR 0.55, 95% CI 0.38–0.79), and decreased macrosomia and large-for-gestational-age neonates in women in all classes of obesity, with the highest decrease for women with class III obesity (greater weight loss adjusted OR 0.15, 95% CI 0.05–0.49; lesser weight loss adjusted OR 0.37, 95% CI 0.15–0.90 for macrosomia). No association between weight loss and low birth weight, small-for-gestational-age neonates, or admission to the neonatal intensive care unit was shown in the different obesity classes.

**CONCLUSION:** Weight loss in obese pregnant women was associated with reduced perinatal risks but not with the rate of low birth weight or small-for-gestational-age neonates in obese women from class III in this affluent region. Stratification of recommended gestational weight gain ranges in obese women should be considered.

(*Obstet Gynecol* 2015;125:566–75)

DOI: 10.1097/AOG.0000000000001677

*From the UC Leuven-Limburg, Department of Healthcare Limburg Hasselt, CRIC, Center for Research and Innovation in Care, Department of Nursing and Midwifery Sciences, University of Antwerp, Antwerp, the Department of Development and Regeneration, KU Leuven, and the Department of Obstetrics & Gynaecology, Division of Mother & Child, University Hospitals, Leuven, and the Flemish Study Centre for Perinatal Epidemiology (SPE), Brussels, Belgium.*

*The Study Centre for Perinatal Epidemiology (SPE) is financed and commissioned by the Flemish Centre for Care and Health (Agentschap Zorg en Gezondheid). Roland Devlieger is senior clinical researcher for FWO Flanders (2010–2015).*

# How to counsel patients when the data is not there



**Table 2.** Adjusted Odds Ratios for Maternal and Neonatal Outcomes in Relation to Weight Change Categories (n=16,944)

Weight Change Category (kg)	Gestational Hypertension (n=1,740)	Emergency Cesarean Delivery (n=2,009)	Macrosomia (n=2,677)
Class I obesity			
Greater weight loss (5 or more)	0.31 (0.11–0.84)	1.06 (0.62–1.78)	0.47 (0.24–0.98)
Lesser weight loss (0–5)	0.46 (0.21–0.99)	0.78 (0.45–1.33)	0.62 (0.37–1.03)
Low gain (0 to less than 5)	0.71 (0.54–0.93)	1.01 (0.80–1.28)	0.79 (0.64–0.97)
Adequate gain (ref) 5–9	1.00	1.00	1.00
Excessive gain (more than 9)	1.49 (1.28–1.74)	1.22 (1.06–1.40)	1.73 (1.53–1.96)
Class II obesity			
Greater weight loss (5 or more)	0.55 (0.23–1.30)	0.24 (0.07–0.78)	0.32 (0.12–0.98)
Lesser weight loss (0–5)	0.80 (0.44–1.44)	0.50 (0.26–0.97)	0.79 (0.45–1.39)
Low gain (0 to less than 5)	0.95 (0.69–1.32)	0.38 (0.28–0.78)	0.87 (0.64–1.19)
Adequate gain (ref) 5–9	1.00	1.00	1.00
Excessive gain (more than 9)	1.33 (1.05–1.69)	1.02 (0.81–1.28)	1.73 (1.39–2.13)
Class III obesity			
Greater weight loss (5 or more)	0.57 (0.26–1.27)	0.78 (0.36–1.68)	0.15 (0.05–0.48)
Lesser weight loss (0–5)	1.27 (0.63–2.35)	1.71 (0.85–2.59)	0.37 (0.15–0.98)
Low gain (0 to less than 5)	1.22 (0.80–1.88)	1.05 (0.64–1.71)	0.67 (0.43–1.02)
Adequate gain (ref) 5–9	1.00	1.00	1.00
Excessive gain (more than 9)	1.39 (0.95–2.03)	1.09 (0.72–1.65)	1.08 (0.75–1.54)

LGA, large for gestational age; SGA, small for gestational age; NICU, neonatal intensive care unit; ref, reference.

OR, odds ratio; CI, confidence interval; P < .05.

Bold indicates Institute of Medicine–inadequate gestational weight gain and  $P < .05$ .

Bold and italicics indicate Institute of Medicine–inadequate gestational weight gain and  $P < .002$  (Bonferroni-corrected).

\* LGA and SGA are adjusted for maternal age and parity.

\* Weight loss categories were combined as a result of small number adjusted for parity, maternal, and gestational age.

0.07–0.78; lesser weight loss adjusted OR 0.50, 95% CI 0.26–0.97; low gain adjusted OR 0.55, 95% CI 0.38–0.79). For neonatal outcomes, weight loss was associated with decreased macrosomia and LGA neonates in all classes of obesity, with the highest effect in women with class III obesity (greater weight loss adjusted OR 0.15, 95% CI 0.05–0.49; lesser weight loss adjusted OR 0.37, 95% CI 0.15–0.90 for macrosomia). Conversely, no association was shown between weight loss and low birth weight, SGA neonates or admission to a NICU in the different classes of obesity (Table 2).

In the multivariate analysis with weight change during pregnancy as a continuous variable, gestational weight gain was inversely related to low birth weight only for class I obese women (adjusted OR 0.97, 95% CI 0.95–0.99) and inversely related to SGA neonates for class I (adjusted OR 0.96, 95% CI 0.95–0.97) and class II (adjusted OR 0.97, 95% CI 0.95–0.98) obese women. Figure 1 shows the predicted probability of all the seven complications of interest, related to gestational weight gain, by class of obesity. The highest predicted probabilities are shown for macrosomia and LGA neonates. Figure 1 demonstrates that the predicted probabilities of macrosomia and LGA neonates are closely related in class I and II of obesity; in

class III, the intercept of macrosomia is lower than for LGA neonates.

As shown in Figure 2, the lowest predicted probability for SGA and LGA combined was associated with a weight gain of 0–5 kg in class I obesity, 0–5 kg weight loss in class II, and up to 15 kg weight loss in class III (additional material can be found as Appendix 1, available online at <http://links.lww.com/AOG/A606>).

## DISCUSSION

In this observational study, obese pregnant women who have a weight gain lower than recommended by the 2009 IOM guidelines have reduced risks of gestational hypertension, emergency cesarean delivery, macrosomia, and LGA neonates. Furthermore, those who lost weight (which was apparent in 5% of obese women) had a lower risk for gestational hypertension, emergency cesarean delivery, macrosomia, and LGA neonates, and this was not at the expense of an increase in low birth weight or SGA neonates.

Most studies cautiously recommend lower weight gains, no weight gain, or even weight loss for obese pregnant women to prevent adverse maternal outcomes.<sup>10–18</sup> On the other hand, studies have until now demonstrated a positive association between

LGA (Greater Than the 90th Percentile)* (n=2,830)	Low Birth Weight (n=246)	SGA (Less Than the 10th Percentile)* (n=1,231)	Admission to NICU (n=317)
0.60 (0.35–1.05)	0.65 (0.16–2.72)	1.48 (0.93–3.34)	0.59 (0.14–2.44)
0.41 (0.23–0.74)	0.83 (0.25–2.72)	1.35 (0.87–2.08)	1.23 (0.49–3.09)
<b>0.72 (0.59–0.88)</b>	1.30 (0.83–2.03)	1.23 (1.00–1.51)	0.61 (0.36–1.05)
1.00	1.00	1.00	1.00
1.59 (0.41–1.78)	0.68 (0.48–0.96)	0.62 (0.33–0.72)	0.93 (0.69–1.27)
0.41 (0.18–0.94)	2.32 (0.65–8.32)	1.90 (0.97–3.73)	0.43 (0.06–3.19)
0.80 (0.48–1.33)	1.92 (0.62–5.96)	1.50 (0.83–2.68)	0.54 (0.13–2.29)
<b>0.73 (0.54–0.98)</b>	1.03 (0.43–2.48)	1.11 (0.76–1.62)	0.49 (0.21–1.13)
1.00	1.00	1.00	1.00
1.71 (0.39–2.08)	0.92 (0.47–1.80)	0.76 (0.35–1.04)	0.83 (0.49–1.39)
<b>0.27 (0.08–0.54)</b>	1.27 (0.24–6.65)	1.53 (0.65–3.60)	
0.60 (0.29–1.23)	0.93 (0.11–7.98)	1.26 (0.46–3.46)	0.20* (0.03–1.53)
0.71 (0.48–1.06)	1.30 (0.41–4.15)	0.97 (0.50–1.88)	0.64 (0.22–1.87)
1.00	1.00	1.00	1.00
1.17 (0.84–1.63)	0.49 (0.14–1.78)	0.73 (0.39–1.36)	1.25 (0.57–2.71)

weight loss and SGA neonates.<sup>14,16,19,20</sup> The results of our study differ from the retrospective analysis of Catalano et al.<sup>19</sup> They included 1,241 singleton term overweight and obese pregnancies from two ongoing trials and concluded that weight loss or gain 5 kg or less was associated with more SGA neonates, lower birth weight, and lower fat and lean mass of the neonate compared with women with more than 5-kg weight gain. In their analysis, overweight and obese women were combined and only 46 of them had reported a weight loss. The mean weight gain in their weight loss and gain category was 1.1 kg (standard deviation [SD] 4.4) compared with 14.4 kg (SD 6.2) in their greater than 5-kg weight gain category. In our analysis, we included only obese women (n=18,053) and reported a weight loss in 854 women. The mean weight loss (n=854) in our analysis was 5.9 kg (SD 5.99); mean weight gain (n=17,199) was 10.76 kg (SD 6.06). Although Catalano et al.<sup>19</sup> aimed to evaluate the association of inadequate gestational weight gain and fetal growth, they included overweight as well as extreme obese pregnant women, but these two groups may have different metabolic rates, which could affect the neonatal outcomes.

Previously, SGA has been associated with weight loss in women with class I and II but not class III obesity.<sup>20,21</sup> Hindle et al.<sup>21</sup> showed that in class II and III women, a gestational weight gain from −4.9 kg to +4.9 kg (compared with those with gestational

weight gain between 5 and 9 kg) did not significantly increase the odds of SGA and had the benefit of reducing macrosomia. Ozan-Frank<sup>22</sup> showed an 11% increase in SGA for each kilogram of weight loss in obese women, but only in those from class I; no difference in SGA was demonstrated in obese women from classes II and III. When they compared obese women with weight gain less than 5 kg with those with adequate gestational weight gain (5–9 kg), no association with SGA was found between the obesity classes. Li et al.<sup>23</sup> also demonstrated no difference in adjusted ORs for SGA and low birth weight if obese women had a weight gain less than 5 kg. These results match ours.

Thus, it appears that an increasing maternal BMI mitigates the effect of weight loss on fetal growth in terms of the probabilities of low birth weight and SGA neonates.

The prevalence of macrosomia has been increasing in our region over the past 15 years (Flemish Study Center for Perinatal Epidemiology, unpublished data) and has consequences for the child at short and long term.<sup>10,24</sup> An estimated optimal gestational weight gain should be defined in relation to the lowest predicted risk of both low birth weight, SGA neonates and macrosomia, LGA neonates, because all of these risks are related to perinatal morbidity and mortality.<sup>24,25</sup> The study of Beyerlein et al.<sup>27</sup> suggested an optimal gestational weight gain range for obese women between −15 and +2 kg for a joint



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Lesser weight loss (0–5)	<b>0.80 (0.48–1.35)</b>	1.92 (0.62–5.96)	1.50 (0.83–2.68)	0.54 (0.13–2.29)
Low gain (0 to less than 5)	<b>0.73 (0.54–0.99)</b>	1.03 (0.43–2.48)	1.11 (0.76–1.62)	0.49 (0.21–1.13)
Adequate gain ([ref] 5–9)	1.00	1.00	1.00	1.00
Excessive gain (more than 9)	1.71 (1.39–2.09)	0.92 (0.47–1.80)	0.76 (0.55–1.04)	0.83 (0.49–1.39)
Class III obesity				
Greater weight loss (5 or more)	<b>0.21 (0.08–0.54)</b>	1.27 (0.24–6.65)	1.53 (0.65–3.60)	
Lesser weight loss (0–5)	<b>0.60 (0.29–1.23)</b>	0.93 (0.11–7.98)	1.26 (0.46–3.46)	0.20 <sup>†</sup> (0.03–1.53)
Low gain (0 to less than 5)	<b>0.71 (0.48–1.06)</b>	1.30 (0.41–4.15)	0.97 (0.50–1.88)	0.64 (0.22–1.87)
Adequate gain ([ref] 5–9)	1.00	1.00	1.00	1.00
Excessive gain (more than 9)	1.17 (0.84–1.63)	0.49 (0.14–1.78)	0.73 (0.39–1.36)	1.25 (0.57–2.71)

LGA, large for gestational age; SGA, small

Data are adjusted odds ratio (95% con-

Bold indicates Institute of Medicine—in

Bold and italics indicates Institute of N

\* LGA and SGA are adjusted for mater

<sup>†</sup> Weight loss categories were combined

weight loss and SGA neonates.<sup>15,16,19,20</sup> The results of

weight gain between 5 and 9 kg) did not significantly



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### Summarize:

- Observational data: “informative, not directive”
- Conclusion: some weight loss during pregnancy in obese women does not seem to be a problem.



## How to counsel patients when the data is not there



### Data Scenario 2: Data-rich:

- large RCTs, Cochrane reviews
- level I evidence
- consensus

Example: preeclampsia



## How to counsel patients when the data is not there



Data-rich:

- Opportunity: compromise
- Potential pitfalls:
  - Overestimating the strength of recommendations
  - Universal adherence ≠ definitive consensus



## How to counsel patients when the data is not there



### Helpful resources:

- Consensus guidelines
  - *Level of evidence / strength of recommendation*
- International guidelines
- Individual studies!



1 / 100

The image shows the front cover of a medical publication. The title "HYPERTENSION IN PREGNANCY" is prominently displayed in large, bold, black and blue capital letters. Below the title, the publisher's name, "The American College of Obstetricians and Gynecologists", is written in smaller white text. At the bottom left, there is a circular logo for "The American College of Obstetricians and Gynecologists" featuring a figure of a pregnant woman. The background of the cover has a textured, blue-toned pattern.



#### BOX E-1. Severe Features of Preeclampsia (Any of these findings)

- Systolic blood pressure of 160 mm Hg or higher, or diastolic blood pressure of 110 mm Hg or higher on two occasions at least 4 hours apart while the patient is on bed rest (unless antihypertensive therapy is initiated before this time)
- Thrombocytopenia (platelet count less than 100,000/microliter)
- Impaired liver function as indicated by abnormally elevated blood concentrations of liver enzymes (to twice normal concentration), severe persistent right upper quadrant or epigastric pain unresponsive to medication and not accounted for by alternative diagnosis, or both
- Progressive renal insufficiency (serum creatinine concentration greater than 1.1 mg/dL or a doubling of the serum creatinine concentration in the absence of other renal disease)
- Pulmonary edema
- New-onset cerebral or visual disturbances

This approach must be used, a determination of 1+ is considered as the cutoff for the diagnosis of proteinuria, unless the health care providers themselves have decided that a determination of 2+ or more is the level of urinary protein and pregnancy outcome in preexisting, massive proteinuria (greater than 5 g) has been eliminated from the consideration of preeclampsia as severe. Also, because fetal growth restriction is managed similarly in pregnant women with and without preeclampsia, it has been removed as a finding indicative of severe pre-eclampsia (Table E-1).

#### Prediction of Preeclampsia

A great deal of effort has been directed at the identification of demographic factors, biochemical analyses, or biophysical findings, alone or in combination, to predict early in pregnancy the later development of preeclampsia. Although there are some encouraging findings, these tests are not yet ready for clinical use.

#### TASK FORCE RECOMMENDATION

- Screening to predict preeclampsia beyond obtaining an appropriate medical history to evaluate for risk factors is not recommended.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Strong

#### Prevention of Preeclampsia

It is clear that the antiebildant vitamin C and vitamin E are not effective interventions to prevent preeclampsia.

- For women with HELLP syndrome at 34–37 weeks gestation, daily low-dose aspirin (80–160 mg) may be undertaken soon after initial maternal stabilization.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women with HELLP syndrome from the gestational age of fetal viability to 36–37 weeks gestation, it is suggested that daily low-dose aspirin be deferred for 24–48 hours after initial maternal stabilization to reduce the risk of hemorrhage in the event of an emergency cesarean delivery.

**Quality of evidence:** Low  
**Strength of recommendation:** Qualified

- For women who have had preeclampsia in a prior pregnancy, preventive measures such as weight loss and exercise should be undertaken to improve maternal and fetal conditions before their next pregnancy. This can be initiated at the time of the first prenatal visit. If the woman has had a normal pregnancy, the administration of magnesium sulfate is suggested.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women with preeclampsia who require analgesics for labor or anesthesia for cesarean delivery, preoperative analgesics should be avoided. For those who require analgesics for establishment of anesthesia, the administration of neuraxial anesthesia (either spinal or epidural) should be considered.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women with severe preeclampsia, it is suggested that invasive hemodynamic monitoring be used to reduce the risk of death.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women in whom preeclampsia, pre-eclampsia, or superimposed preeclampsia is diagnosed, it is suggested that BP be measured in the hospital or clinic. If the woman presents to the office, the BP should be measured in the office.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women with severe preeclampsia, the greatest risk factor is the recognition of preexisting preeclampsia. If the woman has a history of preexisting preeclampsia, she should be referred to a specialist in hypertension and/or nephrology for evaluation and treatment if appropriate. Medical problems such as hypertension and diabetes should be identified and managed. If a woman has a history of medical problems on the pregnancy should be discussed. Medications should be reviewed and discontinued if possible. If a woman has a history of hypertension and/or diabetes, she should be referred to a specialist in hypertension and/or diabetes.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women with severe preeclampsia, it is suggested that the use of low-dose aspirin in the upcoming pregnancy should be suspended.

or adverse outcomes from preeclampsia in unaffected women at high risk for preeclampsia. Only one study has examined the relationship of urinary protein and pregnancy outcome in preexisting, massive proteinuria (greater than 5 g) has been eliminated from the consideration of preeclampsia as severe. The finding of elevated levels of low-density lipoprotein but not total cholesterol or triglycerides in women with preeclampsia has been reported, but this finding is not relevant to a population with adequate calcium intake, such as in the United States. The administration of low-dose aspirin (80–160 mg) to prevent preeclampsia has been examined in meta-analysis of more than 30,000 women, and it appears that there is a slight effect to reduce preeclampsia and associated perinatal complications. The finding of elevated levels of low-density lipoprotein but not total cholesterol or triglycerides in women with preeclampsia has been reported, but this finding is not relevant to populations at very high risk in whom the number of women to treat to achieve the desired outcome will be substantially less. There is no evidence that bed rest or salt restriction reduces preeclampsia risk.

#### TASK FORCE RECOMMENDATIONS

- For women with a medical history of early-onset preeclampsia and planned delivery at less than 34/0.7 weeks of gestation or preeclampsia in more than one prior pregnancy, initiating the administration of daily low-dose aspirin (80–160 mg) as soon as beginning in the late first trimester.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

- For women with a history of more than 20,000 women in randomized trials of aspirin to prevent preeclampsia indicates a small reduction in the incidence and morbidity of preeclampsia and reveals no evidence of acute risks, although long-term follow-up of these women is limited. The decision to treat to have a therapeutic effect is determined by personal choice. In view of maternal safety, a discussion of the use of aspirin in the late first trimester.

**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

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**Quality of evidence:** Moderate  
**Strength of recommendation:** Qualified

TABLE E-1. Diagnostic Criteria for Preeclampsia



## How to counsel patients when the data is not there



### Case:

- 25yo G3P2002 at 37w2d
  - Gestational HTN, stable
  - Knows recommendation for IOL at 37w but *REALLY* wants to avoid induction
  - Asks if she can wait for spontaneous labor



## How to counsel patients when the data is not there



### Helpful resources:

- Consensus guidelines
  - *Level of evidence / strength of recommendation*
- International guidelines
- Individual studies!

### Resources for Ob-Gyns and Women's Health Care Providers

- Task Force Report: Hypertension in Pregnancy.
- Committee Opinion: Emergent Therapy for Acute-Onset, Severe Hypertension During Pregnancy and the Postpartum Period.
- Maternal Safety Bundle for Severe Hypertension in Pregnancy.
- California Preeclampsia Toolkit.

More items...

#### Preeclampsia and Hypertension in Pregnancy: Resource ... - ACOG

[www.acog.org/Womens-Health/Preeclampsia-and-Hypertension-in-Pregnancy](http://www.acog.org/Womens-Health/Preeclampsia-and-Hypertension-in-Pregnancy)

[About this result](#) • [Feedback](#)

#### Hypertension in Pregnancy - ACOG

[www.acog.org/~/media/.../public/HypertensioninPregnancy.pdf](http://www.acog.org/~/media/.../public/HypertensioninPregnancy.pdf)

Home · Resources & Publications · Task Force and Work Group Reports ▾  
Task Force and Work Group Reports; Hypertension in Pregnancy. x  
FOREWORD To address these important issues, the ...

#### [PDF] Hypertension in Pregnancy - ACOG

<https://www.acog.org/~/media/.../public/HypertensioninPregnancy.pdf>

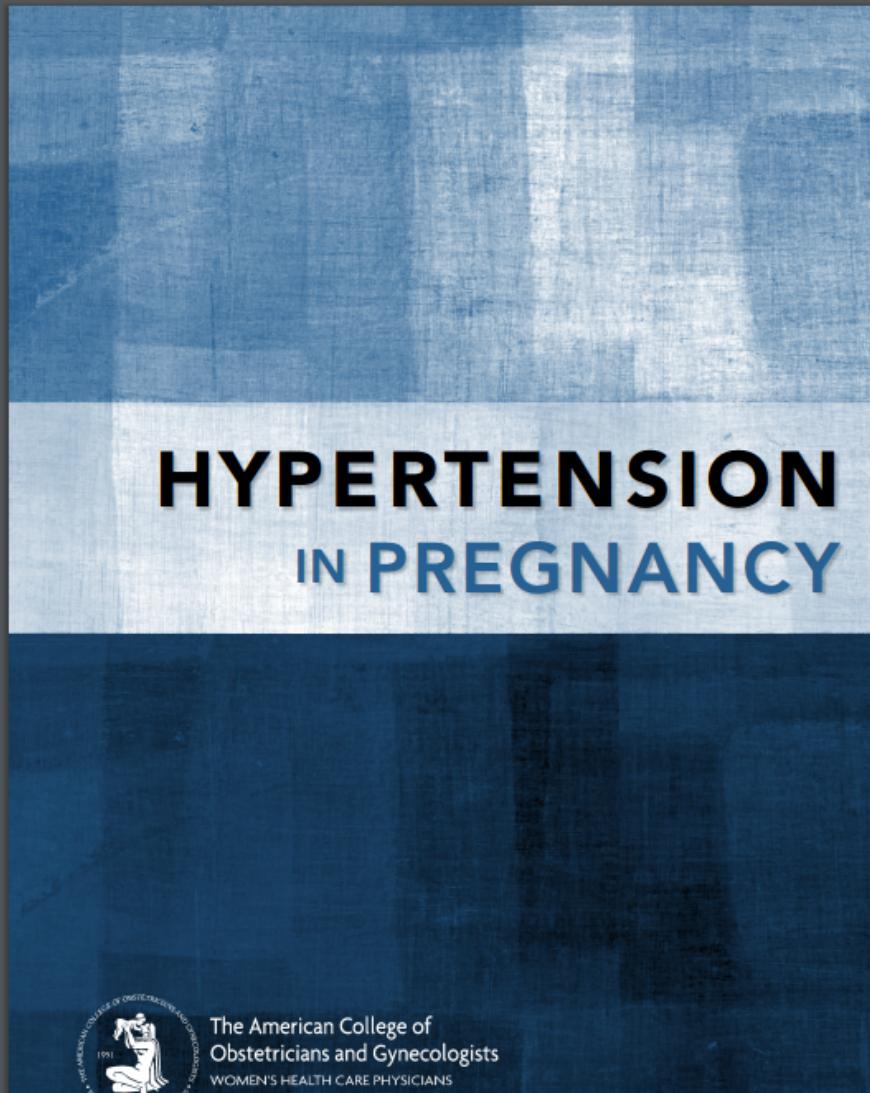
Hypertension in Pregnancy was developed by the Task Force on. Hypertension in ... Hypertension, Pregnancy-Induced—Practice Guideline. WQ 244]. RG575.5.  
You visited this page on 2/1/17.

#### Ob-Gyns Issue Task Force Report on Hypertension in Pregnancy ...

[www.acog.org/~/media/.../public/HypertensioninPregnancy.pdf](http://www.acog.org/~/media/.../public/HypertensioninPregnancy.pdf)

Nov 14, 2013 - Vitamin C or vitamin E to prevent preeclampsia is not recommended. Daily low-dose aspirin to help prevent preeclampsia is suggested in very high-risk women with a history of





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#### TASK FORCE RECOMMENDATIONS

- The close monitoring of women with gestational hypertension or preeclampsia without severe features, with serial assessment of maternal symptoms and fetal movement (daily by the woman), serial measurements of BP (twice weekly), and assessment of platelet counts and liver enzymes (weekly) is suggested.  
*Quality of evidence:* Moderate  
*Strength of recommendation:* Qualified
- For women with gestational hypertension, monitoring BP at least once weekly with proteinuria assessment in the office and with an additional weekly measurement of BP at home or in the office is suggested.  
*Quality of evidence:* Moderate  
*Strength of recommendation:* Qualified
- For women with mild gestational hypertension or preeclampsia with a persistent BP of 160 mm Hg systolic or 110 mm Hg diastolic, delivery rather than continued observation is suggested.  
*Quality of evidence:* Moderate  
*Strength of recommendation:* Qualified
- For women with gestational hypertension or preeclampsia without severe features at or beyond 37 0/7 weeks of gestation, delivery rather than continued observation is suggested.  
*Quality of evidence:* Low  
*Strength of recommendation:* Qualified
- For women with mild gestational hypertension or preeclampsia with a persistent BP of 160 mm Hg systolic or 110 mm Hg diastolic, delivery rather than continued observation is suggested.  
*Quality of evidence:* Moderate  
*Strength of recommendation:* Qualified
- For women with gestational hypertension or preeclampsia without severe features, delivery rather than bed rest not be prescribed.  
*Quality of evidence:* Low  
*Strength of recommendation:* Qualified
- The task force acknowledged that there may be circumstances in which different levels of rest, either at home or in a hospital, may be indicated for individual women. Previous recommendations do not cover all circumstances, such as those involving overall physical activity and manual labor.
- † Women may need to be hospitalized for reasons other than bed rest, such as for maternal and fetal surveillance. The task force agreed that hospitalization for maternal and fetal surveillance is resource intensive and should be considered as a priority for research and future recommendations.
- For women with preeclampsia without severe features, use of ultrasonography to assess fetal growth and antenatal testing to assess fetal status is suggested.  
*Quality of evidence:* Moderate  
*Strength of recommendation:* Qualified
- For women with preeclampsia receiving expectant management at 34 0/7 weeks or less of gestation, the administration of corticosteroids for fetal lung maturity benefit is recommended.  
*Quality of evidence:* High  
*Strength of recommendation:* Strong

#### EXECUTIVE SUMMARY

5

ot there





## How to counsel patients when the data is not there



### Helpful resources:

- Consensus guidelines
  - *Level of evidence / strength of recommendation*
- International guidelines
- Individual studies!



## How to counsel patients when the data is not there



- Recommendations are made by multiple societies:
  - ACOG
  - WHO
  - NICE (UK)
  - SOGC (Canada)

## How to counsel patients when the data is not there



- ACOG:

- For women with mild gestational hypertension or preeclampsia without severe features at or beyond 37 0/7 weeks of gestation, delivery rather than continued observation is suggested.

*Quality of evidence:* Moderate

*Strength of recommendation:* Qualified

- SOGC:

89. For women with gestational hypertension (without preeclampsia) at  $\geq 37+0$  weeks' gestation, delivery within days should be discussed. (I-B)

- NICE:

- 1.4.2.1 Do not offer birth before 37 weeks to women with gestational hypertension whose blood pressure is lower than 160/110 mmHg, with or without antihypertensive treatment.
- 1.4.2.2 For women with gestational hypertension whose blood pressure is lower than 160/110 mmHg after 37 weeks, with or without antihypertensive treatment, timing of birth, and maternal and fetal indications for birth should be agreed between the woman and the senior obstetrician.

- WHO:

In women with mild pre-eclampsia or mild gestational hypertension at term, induction of labour is recommended.

Moderate

Weak



## How to counsel patients when the data is not there



### Helpful resources:

- Consensus guidelines
  - *Level of evidence / strength of recommendation*
- International guidelines
- Individual studies!



# How to counsel patients when the data is not there



PubMed US National Library of Medicine National Institutes of Health

PubMed gestational hypertension expectant management Advanced Search Help



**PubMed**

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[Induction of labour versus expectant monitoring for gestational hypertension or mild pre-eclampsia after 36 weeks' gestation \(HYPITAT\): a multicentre, open-label randomised controlled trial.](#)

Koopmans CM, Bijlenga D, Groen H, Vijgen SM, Aarnoudse JG, Bekedam DJ, van den Berg PP, de Boer K, Burggraaff JM, Bloemenkamp KW, Drogtrip AP, Franx A, de Groot CJ, Huisjes AJ, Kwee A, van Loon AJ, Lub A, Papatsonis DN, van der Post JA, Roumen FJ, Scheepers HC, Willekes C, Mol BW, van Pampus MG; HYPITAT study group..

Lancet. 2009 Sep 19;374(9694):979-88. doi: 10.1016/S0140-6736(09)60736-4.

PMID: 19656558

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# Induction of labour versus expectant monitoring for gestational hypertension or mild pre-eclampsia after 36 weeks' gestation (HYPITAT): a multicentre, open-label randomised controlled trial



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## Summary

**Background** Robust evidence to direct management of pregnant women with mild hypertensive disease at term is scarce. We investigated whether induction of labour in women with a singleton pregnancy complicated by gestational hypertension or mild pre-eclampsia reduces severe maternal morbidity.

**Methods** We undertook a multicentre, parallel, open-label randomised controlled trial in six academic and 32 non-academic hospitals in the Netherlands between October, 2005, and March, 2008. We enrolled patients with a singleton pregnancy at 36–41 weeks' gestation, and who had gestational hypertension or mild pre-eclampsia. Participants were randomly allocated in a 1:1 ratio by block randomisation with a web-based application system to receive either induction of labour or expectant monitoring. Masking of intervention allocation was not possible. The primary outcome was a composite measure of poor maternal outcome—maternal mortality, maternal morbidity (eclampsia, HELLP syndrome, pulmonary oedema, thromboembolic disease, and placental abruption), progression to severe hypertension or proteinuria, and major post-partum haemorrhage (>1000 mL blood loss). Analysis was by intention to treat and treatment effect is presented as relative risk. This study is registered, number ISRCTN08132825.

**Findings** 756 patients were allocated to receive induction of labour (n=377 patients) or expectant monitoring (n=379). 397 patients refused randomisation but authorised use of their medical records. Of women who were randomised, 117 (31%) allocated to induction of labour developed poor maternal outcome compared with 166 (44%) allocated to expectant monitoring (relative risk 0·71, 95% CI 0·59–0·86, p<0·0001). No cases of maternal or neonatal death or eclampsia were recorded.

**Interpretation** Induction of labour is associated with improved maternal outcome and should be advised for women with mild hypertensive disease beyond 37 weeks' gestation.

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See Comment page 951

\*Collaborators listed at end of paper

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## How to counsel patients when the data is not there

	Induction of labour (n=377)	Expectant monitoring (n=379)	Relative risk (95% CI; p value)	Absolute risk reduction (95% CI)
<b>Severe hypertension measured twice (mm Hg)</b>				
Systolic BP	26 (7%)	44 (12%)	0.60 (0.38–0.95; 0.03)	4.71% (0.57–8.92)
Diastolic BP	28 (7%)	50 (13%)	0.56 (0.36–0.87; 0.01)	5.77% (1.42–10.16)
<b>Drugs</b>				
Oral antihypertensive	67 (18%)	111 (29%)	0.61 (0.47–0.80; <0.0001)	11.52% (5.48–17.45)
Intravenous antihypertensive	13 (3%)	39 (10%)	0.34 (0.18–0.62; <0.0001)	6.84% (3.28–10.59)
Intravenous anticonvulsive	24 (6%)	46 (12%)	0.53 (0.33–0.84; 0.01)	5.77% (1.64–9.98)
<b>Maternal hospital care</b>				
Intensive care	6 (2%)	14 (4%)	0.41 (0.16–1.07; 0.059)	NS
Medium care	14 (4%)	15 (4%)	0.90 (0.44–1.84; 0.777)	NS
Maternal ward	340 (90%)	319 (84%)	1.03 (0.99–1.07; 0.145)	NS
Unknown	17 (5%)	31 (8%)	NA	NA
<b>Duration of hospital stay (days)</b>	2.0 (1.0–3.0)	2.0 (1.0–4.0)	0.12†	NA

## How to counsel patients when the data is not there

	Induction of labour (n=377)	Expectant monitoring (n=379)	Relative risk (95% CI; p value)
Spontaneous	273 (72%)	253 (67%)	1.09 (0.99–1.19; 0.091)
Vaginal instrumental delivery	50 (13%)	54 (14%)	0.93 (0.65–1.33; 0.694)
Caesarean section	54 (14%)	72 (19%)	0.75 (0.55–1.04; 0.085)*
Clinical features indicating that caesarean section was needed			
Arrest of first stage of labour	15 (28%)	24 (33%)	NA
Arrest of second stage of labour	3 (6%)	7 (10%)	NA
Failed instrumental delivery	4 (7%)	2 (3%)	NA
Fetal distress	17 (31%)	20 (27%)	NA
Failure to progress and fetal distress	12 (22%)	8 (11%)	NA
Maternal complication	2 (4%)	7 (10%)	NA
Elective	1 (2%)	4 (6%)	NA

Data are number of patients (%), unless otherwise indicated. NA=not applicable. \*Absolute risk reduction is 4.67% (95% CI -0.65 to 9.98).

Table 4: Method of delivery

## How to counsel patients when the data is not there

	Induction of labour (n=377)	Expectant monitoring (n=379)	Relative risk (95% CI; p value)
Birthweight (g)	3220 (2890–3565)	3490 (3080–3810)	<0.0001*
Composite adverse neonatal outcome	24 (6%)	32 (8%)	0.75 (0.45–1.26; 0.276)†
Fetal deaths	0	0	NA
Apgar score of <7 after 5 min	7 (2%)	9 (2%)	0.79 (0.30–2.09; 0.632)
Arterial pH <7.05‡	9 (3%)	19 (6%)	0.46 (0.21–1.00; 0.043)§
Admission to intensive care	10 (3%)	8 (2%)	1.26 (0.50–3.15; 0.625)
Neonatal hospital care			
Medium care	68 (18%)	69 (18%)	0.99 (0.73–1.34; 0.952)
High care	12 (3%)	10 (3%)	1.21 (0.53–2.76; 0.656)
Intensive care	10 (3%)	8 (2%)	1.26 (0.50–3.15; 0.625)
Duration of stay in a neonatal medium, high, or intensive care unit (days)	3.0 (2.0–6.0)	4.0 (2.8–7.0)	0.077*



## How to counsel patients when the data is not there



### Summarize:

- Widespread consensus: delivery ~37w
  - Varying language:
    - ACOG: “delivery is suggested”
      - data quality: moderate; strength of recommendation: qualified
    - SOGC: “delivery should be discussed”
    - NICE: “timing of delivery should be agreed upon by the patient and her obstetrician”
    - WHO: “delivery is recommended”
      - Data quality: moderate; strength of recommendation: weak



## How to counsel patients when the data is not there



- Individual study: HYPITAT trial
  - Expectant management = 12.5% absolute risk increase of “maternal composite morbidity”
    - No deaths, no cases of eclampsia, no abruption
    - IOL does *not* increase risk of Cesarean or operative vaginal delivery
    - No difference in short term neonatal outcomes

Conclusion: Delivery is recommended, but the risk of expectant management is not egregious. Compromise at 39w?



## How to counsel patients when the data is not there



### Data Scenario 3: Data-useless:

- Definition of success may vary
- Driven by values and local resources, not evidence
- Patients may have high degree of emotional investment

Example: periviability, TOLAC



## How to counsel patients when the data is not there



### Data-useless:

- Opportunity: requires you to spend time, get to know the patient's values
- Potential pitfalls:
  - Value laden language
  - Unclear role of statistics



## How to counsel patients when the data is not there



### Case:

- 38yo G3P2 at 37w
  - First pregnancy: term NSVD
  - Most recent pregnancy: cesarean for decels
  - BMI 35
  - Preeclampsia without severe features
  - SVE: long/closed/high
  - Wants TOLAC, was told she had a 75% chance of VD



## How to counsel patients when the data is not there



Things you know:

1. Successful vaginal delivery is safer than cesarean
2. Planned cesarean is better than failed TOLAC

*or*

Morbidity:

vaginal delivery < Elective repeat CD < failed TOLAC

# How to counsel patients when the data is not there



Google

NICHHD VBAC calculator

All News Images Videos Shop

About 3,840 results (1.04 seconds)

This calculator is based on the equat

[https://mfmu.bsc.gwu.edu/PublicBSC/MFMU/VAGINAL\\_BIRTH\\_AFTER\\_CESAREAN](https://mfmu.bsc.gwu.edu/PublicBSC/MFMU/VAGINAL_BIRTH_AFTER_CESAREAN) ... Developer (MFMU), "Development of a nomogram for predicti You've visited this page 2 times. Last visit: 2/2/17

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What is vaginal birth after cesarean (

<https://www.nichd.nih.gov/health/topics/labor->Please note that this calculator only determines the birth after cesarean delivery: Deciding on a trial of You visited this page on 2/1/17.

Vaginal Birth After Cesarean (VBAC)

<https://innovations.ahrq.gov/.../vaginal-birth-af> Apr 10, 2013 - Vaginal Birth After Cesarean (VBAC) Development (NICHD) Maternal-Fetal Medicine Uni You've visited this page 2 times. Last visit: 2/1/17

VAGINAL BIRTH AFTER CESAREAN

Height & weight optional; enter them to automatically calculate BMI

Maternal age	<input type="text" value="38"/> years
Height (range 54-80 in.)	<input type="text"/> in
Weight (range 80-310 lb.)	<input type="text"/> lb
Body mass index (BMI, range 15-75)	<input type="text" value="35"/> kg/m <sup>2</sup>
African-American?	<input type="radio"/> no
Hispanic?	<input type="radio"/> no
Any previous vaginal delivery?	<input type="radio"/> yes
Any vaginal delivery since last cesarean?	<input type="radio"/> no
Indication for prior cesarean of arrest of dilation or descent?	<input type="radio"/> no

[CLICK HERE](#) for calculator based on information available at admission.

This calculator is based on the equation published in the article "Development of a nomogram for prediction of vaginal birth after cesarean" cited below. It is designed for educational use and is based on a population of women who received care at the hospitals within the MFMU Network. Responsibility for its correct application is accepted by the end user.

Grobman WA, Lai Y, Landon MB, Spong CY, Leveno KJ, Rouse DJ, Varner MW, Moawad AH, Caritis SN, Harper M, Wapner RJ, Sorokin Y, Miodovnik M, Carpenter M, O'Sullivan MJ, Sibai BM, Langer O, Thorp JM, Ramin SM, Mercer BM; National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU), "Development of a nomogram for prediction of vaginal birth after cesarean delivery," *Obstetrics and Gynecology*, volume 109, pages 806-12, 2007.

VAGINAL BIRTH AFTER CESAREAN

Predicted chance of vaginal birth after cesarean: **74.3%**

95% confidence interval: **[70.4%, 77.9%]**



## How to counsel patients when the data is not there

VAGINAL BIRTH AFTER CESAREAN  
Height & weight optional; enter them to automatically calculate BMI

Maternal age	<input type="text" value="38"/> years
Height (range 54-80 in.)	<input type="text"/> in
Weight (range 80-310 lb.)	<input type="text"/> lb
Body mass index (BMI, range 15-75)	<input type="text" value="35"/> kg/m <sup>2</sup>
African-American?	<input type="text" value="no"/>
Hispanic?	<input type="text" value="no"/>
Any previous vaginal delivery?	<input type="text" value="yes"/>
Any vaginal delivery since last cesarean?	<input type="text" value="no"/>
Indication for prior cesarean of arrest of dilation or descent?	<input type="text" value="no"/>
Estimated gestational age at delivery	<input type="text" value="37"/> weeks
Hypertensive disease of pregnancy	<input type="text" value="yes"/>
Effacement	<input type="text" value="0"/> %
Dilation	<input type="text" value="0"/> cm
Station (0:Floating/Ballotable, 1:-5, 2:-4, 3:-3, 4:-2, 5:-1, 6:0, 7:+1, 8:+2, 9:+3)	<input type="text" value="3"/>
Labor induction	<input type="text" value="yes"/>
<input type="button" value="Calculate"/>	

VAGINAL BIRTH AFTER CESAREAN

Predicted chance of vaginal birth after cesarean: **58.1%**

Warning: The confidence interval cannot be provided since the model was fitted by a pseudo likelihood approach.

This calculator is based on the equation published in the article "Does information available at the time of admission for delivery improve prediction of successful birth after cesarean?" cited below. It is designed for educational use and is based on a population of women who received care at the hospitals within the MFMU Network. Responsibility for its correct application is accepted by the end user.

Grobman WA, Lai Y, Landon MB, Spong CY, Leveno KJ, Rouse DJ, Varner MW, Moawad AH, Simhan HN, Harper M, Wapner RJ, Sorokin Y, Miodovnik M, Carpenter M, O'Sullivan MJ, Sibai BM, Langer O, Thorp JM, Ramin SM, Mercer BM: the Eunice Kennedy Shriver



## How to counsel patients when the data is not there



### A word about population numeracy

**IT IS BAD**



## How to counsel patients when the data is not there



### Communicating Risk:<sup>2</sup>

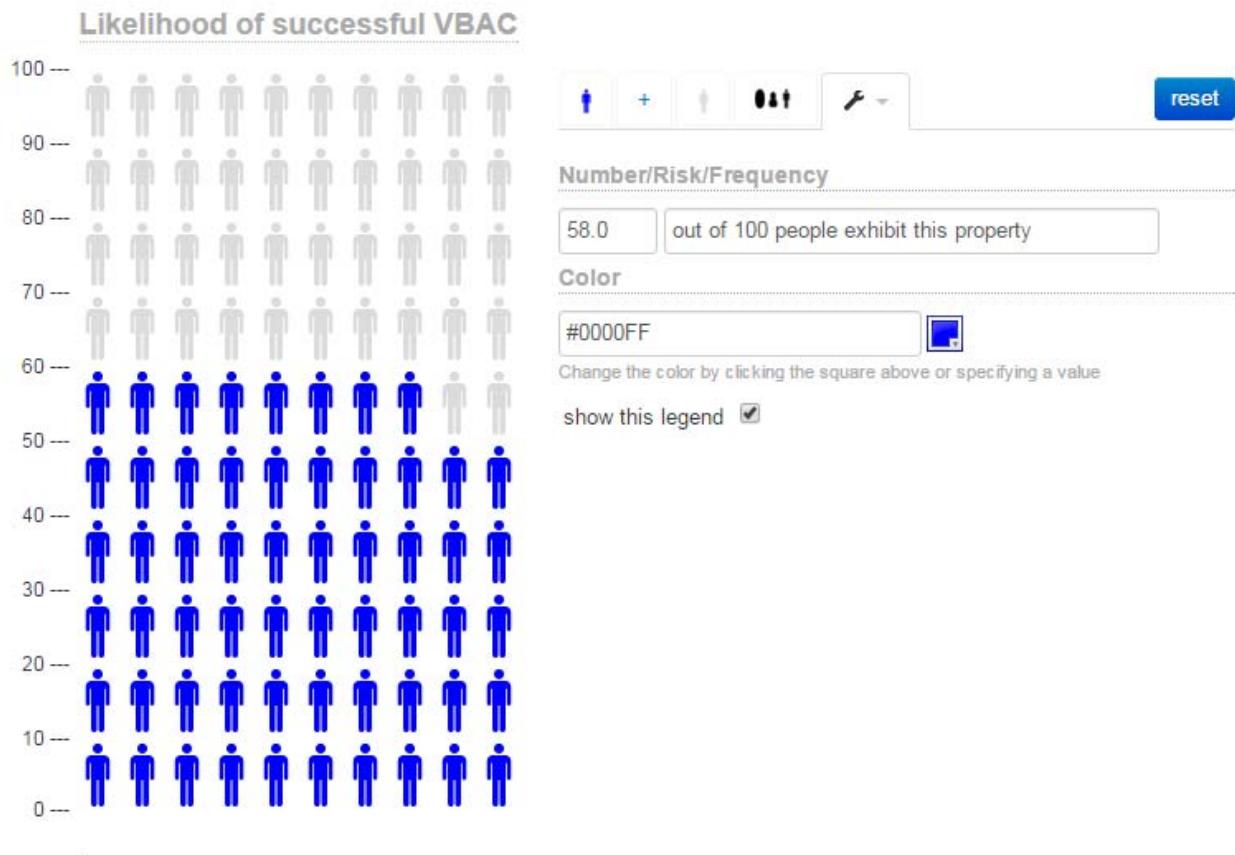
- Use *absolute risks* (ARs), not *relative risks* (RRs) or NNT
- Percentage *Framing*
- Visual aids / graphs
  - Incremental risk
- Order of presentation- “recency effect”

## How to counsel patients when the data is not there



### Communicating Risk:

- [Clinician.iconarray.com](http://Clinician.iconarray.com)





## How to counsel patients when the data is not there



### Resources:

- Icon array/pictograph generator: [Clinician.iconarray.com](http://Clinician.iconarray.com)
- TOLAC calculator:  
<https://mfmu.bsc.gwu.edu/PublicBSC/MFMU/VGBirthCalc/vagbirth.html>
  - (or, just Google: “NICHD VBAC calculator”)
- ACOG HTN in pregnancy guidelines:  
<https://www.acog.org/~media/Task%20Force%20and%20Work%20Group%20Reports/public/HypertensioninPregnancy.pdf>
  - (or, Google: “ACOG hypertension in pregnancy guidelines”)
- NICE (UK) guidelines: [www.nice.org.uk](http://www.nice.org.uk)
- SOGC Practice guidelines: <https://sogc.org/clinical-practice-guidelines.html>



## How to counsel patients when the data is not there



### Reading list:

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