

CESAREAN BIRTH UTILIZATION

**Quality Improvement
Project**



*Birthrisk*TM



Quality Improvement Project Cesarean Birth Utilization

The goal of our Quality Improvement (QI) project is to improve cesarean birth utilization. Cesarean birth utilization is a measure that takes into account the population of women who are giving birth. Hospitals that serve a population of women that have more risk factors for cesarean birth than the average hospital may have a higher than average unadjusted cesarean birth rate. However, it is very possible that a risk adjusted analysis of that hospital's birth data could reveal that they actually have appropriate cesarean birth utilization. Our QI project contains two parts; a preliminary analysis and an optional detailed analysis of your birth data. **The preliminary analysis** will provide you with a risk adjusted analysis of your hospital's birth data and is **currently being offered at no charge.**

The Joint Commission's Core Measure PC-02:Cesarean Birth ignores some of the most significant risk factors for cesarean birth as it is simply an unadjusted Nulliparous Term Singleton Vertex (NTSV) cesarean birth rate. The goal of the preliminary analysis is to help you to evaluate your NTSV cesarean birth rate by comparing your patient population to similar patient populations across the country.

In addition to evaluating your NTSV cesarean birth rate the preliminary analysis will allow you to provide feedback to the Joint Commission regarding the validity of their measure. On our home page there is a link to a 47 minute video presentation. The first half of the video provides the background and a complete analysis of why Core Measure PC-02:Cesarean Birth is not a useful cesarean birth measure. The second half of the video provides the scientific background behind the development and validation of our Birthrisk Cesarean Birth Measure.

If the preliminary analysis reveals that your cesarean birth utilization could use some improvement then we suggest that you consider subscribing to our detailed analysis. Obtaining a detailed analysis of your birth data will provide you with the reports that can be used to make and monitor meaningful changes to your cesarean birth utilization.

A subscription empowers you with our database of almost 10 million birth records from both nulliparous and multiparous women. As noted in our 47 minute presentation, including multiparous women is mandatory when creating a detailed analysis. The addition of your results to our database will provide you with a robust suite of reports including:

- Detailed analysis of deviations in cesarean birth utilization
- Actual and expected cesarean birth rates
- Birthrisk Cesarean Birth Measure for each obstetrical care provider
- Standard, detailed and custom reports
- Comparisons to other hospitals in your county or state (if available)

A subscription provides access to your suite of reports for a period of time equal to the period of time for which births were submitted (i.e. 3 months, 6 months, 1 year). The current cost of a subscription in 2018 is \$8/birth for data submitted in an electronic format (i.e. spreadsheet). The preliminary analysis is currently being offered at no charge.

Our QI project is easy to setup and accomplish. We feel that it is mandatory to view the 47 minutes presentation on our home page in order to fully understand the concept of cesarean birth utilization and the Birthrisk Cesarean Birth Measure. We would be happy to address any questions that come up after viewing the presentation.

Obtaining data from every birth is accomplished either through your existing electronic medical record (EMR) or from the U.S. standard certificate of live birth. We require the following data elements which are all currently reported on the U.S. Certificate of Live Birth (item #):

Time of this Birth (2), Date of this Birth (4), Facility Name (5), Maternal Date of birth (8b), County of Birth (7), Name of Obstetrical Care Provider (27), Was mother transferred to your hospital for this birth (28), Maternal Height (31), Prepregnancy Maternal Weight (32), Maternal weight at this birth (33), Number of previous live births (35a,35b), History of previous cesarean (41), Precipitous or prolonged labor (44), Induction or Augmentation of labor or Non-Vertex presentation (45), Fetal Presentation (46c), Route and Method of Birth and if Trial of Labor (46d), Newborn weight (49), Gestational age (50), and Plurality (52)

In order to provide you with your birth data analysis we need you to provide us with a digital file which has the above data elements. This should be possible either through the software that you use to transmit birth certificate data or through your EMR. We will need to contact the person at your institution who is providing the data so that we can confirm that the correct data elements are being captured. Once we confirm that obtaining the data is possible we will execute a HIPAA required standard data use agreement for the release of a limited data set.

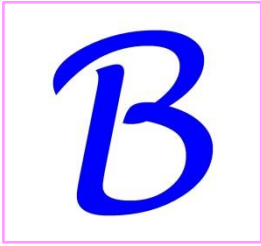
Please contact us at ProviderInfo@Birthrisk.com if you have any questions or if you wish to conduct a QI project at your institution.

Sincerely,

A handwritten signature in black ink, appearing to read "Gustavo San Román", with a stylized flourish at the end.

Gustavo San Román, MD, FACOG

p.s. The remainder of this brochure contains an example of a preliminary report as well as some examples of the reports available through a subscription to our detailed analysis.



Birthrisk.com, LLC
5225-70 Route 347
Port Jefferson Station, NY 11776

Dr. M. Welby
Chief Medical Officer
2018 Main Street
Anytown, Anystate 12018

Dear Dr. Welby,

Birthrisk.com, LLC performed an analysis of your hospital's birth data for births that occurred from January 1, 2017 to December 31, 2017 and found that the birth data contained 1,525 Nulliparous Term Singleton Vertex (NTSV) patients. Your results were compared to the National Center for Health Statistics, Birth Data Files for 2015 & 2016. A detailed analysis of this data is found later in this report. A summary of your data reveals the following:

Your hospital has NTSV patients with an average maternal age of 30.1 years old which is significantly older than the national average of 26.5 years old ($p < 0.001$). Your hospital had an unadjusted NTSV cesarean birth rate of 28.9%. If your hospital had the national average cesarean birth rate for each age group then your expected cesarean birth rate would be 29.6%.

Therefore, your hospital's NTSV cesarean birth rate is not significantly different than the expected rate that would be achieved by the average hospital in the United States that had the same maternal age distribution as your hospital ($p = 0.700$).

These finding DO NOT validate the use of an unadjusted NTSV rate as a measure of your hospital's true performance.

Your hospital has patients with an average maternal prepregnancy BMI of 26.2 kg/m² which is not significantly different than the national average of 25.9 kg/m² ($p = 0.100$).

Therefore, your hospital's significantly older average maternal age along with average maternal BMIs does not support the concept that hospitals that have older patients have patients with lower BMIs.

These finding DO NOT validate the claim that hospitals with a high maternal age population also have a low body mass index.

We hope that you find this information useful and that it can be used to improve the care that is provided to women who will give birth.

Sincerely,

Gustavo San Román, MD, FACOG

Overall Comparison to National Birth Data:

National Center for Health Statistics, Birth Data File for 2015 & 2016.

Available at http://www.cdc.gov/nchs/data_access/vitalstatsonline.htm

Birthrisk.com's analysis is within 0.04% of the number published in National Vital Statistics Reports Volume 67, Number 1

	2015	2016	Your Hospital
Total Birth Records	3,988,733	3,956,112	4,699
Unknown Parity	20,524	15,958	19
Multiparous	2,438,824	2,436,655	2,895
Unknown Weeks	763	819	1
< 37 or > 42 Weeks	140,860	141,690	168
Multiple Gestation	12,568	11,886	14
Unknown Presentation	21,122	6,438	7
Non-Vertex Presentation	62,071	59,424	70
Missing Route of Birth	367	213	0
Total NTSV Birth Records	1,291,634	1,283,029	1,525
Number of Cesarean Births	332,257	329,890	440
Total NTSV Cesarean Birth Rate	25.7%	25.7%	28.9%
Average Maternal Age (years)	26.3	26.5	30.1
Missing Maternal Height	33,898	7,211	8
Missing Maternal Prepregnancy Weight	23,429	22,520	24
Total NTSV Birth Records with BMI	1,234,307	1,253,298	1,493
Average Maternal Prepregnancy BMI (kg/m²)	25.8	25.9	26.2
Missing Induction Yes/No	211	506	2
Missing Maternal Weight at Birth	11,046	10,302	12
Missing Newborn Weight	329	417	1
Complete NTSV Birth Records	1,222,721	1,242,073	1,478
Number of Cesarean Births	313,589	319,302	427
Complete NTSV Cesarean Birth Rate	25.6%	25.7%	28.9%
Average values for Complete NTSV Birth Records			
Average Maternal Age (years)	26.2	26.5	30.1
Average Maternal Prepregnancy BMI (kg/m ²)	25.8	25.8	26.2
Average Newborn Weight (grams)	3,337.9	3,335.8	3,350.5
Average Maternal Weight Gain (pounds)	32.5	32.2	35.1
Average Maternal Height (inches)	64.2	64.2	63.9
Average Gestational Age (weeks)	39.2	39.2	39.1

Maternal Age Analysis Report

RESULTS BY AGE:

This is the Nulliparous Term Singleton Vertex (NTSV) pregnancy birth data obtained from the National Center for Health Statistics divided into age strata. The Joint Commission claims that the effect of maternal BMI will cancel out the effect of maternal age.

The national average age for NTSV patients was 26.5.

The average NTSV age at your hospital was 30.1.

Your hospital's NTSV patients are significantly older than the national average (p= <0.001).

NATIONAL 2016 NTSV BIRTHS				
Age Group	# of Cesareans	# of Patients	Ave Age	Cesarean Rate
< 20	25,451	154,020	17.9	16.5%
20 - 24	78,401	360,362	22.0	21.8%
25 - 29	94,082	369,601	27.0	25.5%
30 - 34	83,334	280,326	31.7	29.7%
35 - 39	38,226	98,782	36.4	38.7%
> 39	10,396	19,938	41.6	52.1%
Totals	329,890	1,283,029	26.5	25.7%

This is the NTSV age distribution at your hospital and a calculation of the expected cesarean birth rate if your hospital provided the same cesarean birth utilization by age group as the national average.

Your Hospital		Your Hospital	National Average
AGE Distribution		% Dist.	% Dist.
Age Group	# of Patients	% Dist.	% Dist.
< 20	25	1.6%	12.0%
20 - 24	200	13.1%	28.1%
25 - 29	500	32.8%	28.8%
30 - 34	450	29.5%	21.8%
35 - 39	300	19.7%	7.7%
> 39	50	3.3%	1.6%
Totals	1,525	100.0%	100.0%

			Hospital Actual	National Expected
Age Group	# of Cesareans	# of Patients	Cesarean Rate	Cesarean Rate
< 20	3	25	12.0%	16.5%
20 - 24	40	200	20.0%	21.8%
25 - 29	125	500	25.0%	25.5%
30 - 34	134	450	29.8%	29.7%
35 - 39	115	300	38.3%	38.7%
> 39	23	50	46.0%	52.1%
			Actual	Expected
Totals	440	1,525	28.9%	29.6%

Your hospital has NTSV patients with a maternal age distribution that is significantly older than the national average and had an unadjusted NTSV cesarean birth rate of 28.9%.

If your hospital had the national average cesarean birth rate for each age group then your expected cesarean birth rate would be 29.6%. Therefore, your hospital's NTSV cesarean birth rate is not significantly different than the expected rate that would be achieved by the average hospital in the United States that had the same maternal age distribution as your hospital (p=0.700).

These finding DO NOT validate the use of an unadjusted NTSV rate as a measure of your hospital's true performance.

Maternal BMI Analysis Report

RESULTS BY BMI:

This is the Nulliparous Term Singleton Vertex (NTSV) pregnancy birth data obtained from the National Center for Health Statistics divided into Body Mass Index (BMI) strata.

The national average BMI for NTSV patients was 25.9.

The average NTSV BMI at your hospital was 26.2.

Your hospital's NTSV patients are not significantly thinner than the national average (p= 0.100).

BMI reported in kg/m²

NATIONAL 2016 NTSV BIRTHS				
BMI Group	# of Cesareans	# of Patients	Ave BMI	Cesarean Rate
< 20	19,295	119,651	24.9	16.1%
20 - 24	105,172	517,207	26.2	20.3%
25 - 29	90,168	332,419	26.1	27.1%
30 - 34	52,053	156,485	25.7	33.3%
35 - 39	29,672	75,251	26.2	39.4%
> 39	25,619	52,285	26.3	49.0%
Totals	321,979	1,253,298	25.9	25.7%

This is the actual NTSV BMI distribution at your hospital compared to the national average.

BMI Dist.	# of Patients	Actual % Dist.	National Average % Dist.	z-test p Value
< 20	146	9.8%	9.5%	0.986
20 - 24	618	41.4%	41.3%	0.992
25 - 29	390	26.1%	26.5%	0.903
30 - 34	192	12.9%	12.5%	0.954
35 - 39	83	5.6%	6.0%	< 0.001
> 39	64	4.3%	4.2%	0.786
Totals	1,493	100.0%	100.0%	

AVERAGE BMI by AGE				
Age	# of Patients	Actual Ave BMI	National Ave BMI	t-test p Value
< 20	25	25.0	24.9	0.952
20 - 24	196	26.2	26.2	0.799
25 - 29	489	26.0	26.1	0.678
30 - 34	440	26.0	25.7	0.373
35 - 39	294	27.2	26.2	0.005
> 39	49	26.3	26.3	0.979
Totals	1,493	26.2	25.9	0.100
		Average BMI		

The Joint Commission claims that the effect of maternal BMI will cancel out the effect of maternal age. For this to be true hospitals with older patients would have to have thinner patients across all age groups and hospitals with younger patients would have to have heavier patients across all age groups.

Your hospital has patients with a maternal age distribution that is significantly older than the national average but has an average maternal prepregnancy BMI that is not significantly different than the national average. Your hospital's distribution and average of maternal BMIs do not support the concept that hospitals that have older patients have patients with lower BMIs.

These finding DO NOT validate the claim that hospitals with older patients have thinner patients.



History of Core Measure PC-02:Cesarean Birth

In 2006 Dr. Elliot Main et al., published in the American Journal of Obstetrics and Gynecology an article titled “Is there a useful cesarean birth measure? Assessment of the nulliparous term singleton vertex cesarean birth rate as a tool for obstetric quality improvement”. In this article they stated “Our study also confirms that the effects of maternal age on NTSV CB are quite significant and start from an early maternal age” as well as “In some hospitals with particularly skewed age distributions, such age adjustments can make a major difference in the NTSV CB rates.” This article used a technique called direct standardization to make the “age adjustments” (aka maternal age risk adjustment). This work was endorsed by the National Quality Forum (NQF) in 2008 and in 2010 the Joint Commission adopted the NTSV cesarean birth rate with the direct standardization maternal age risk adjustment as Core Measure PC-02:Cesarean Birth.

In 2010 my critical analysis of this measure revealed a fatal flaw in the direct standardization technique that renders the measure useless for most hospitals. I spent five years attempting to inform the Joint Commission and American College of Obstetrics and Gynecology of this flaw. It wasn't until July of 2015 that the Joint Commission responded to my concerns regarding the fatal flaw in the maternal age risk adjustment. They finally confirmed my findings and it was my analysis that resulted in their statement to the NQF in section 2b4.2 of their 2016 submission “The decision to remove all risk-adjustment from this measure was made based on analysis of data on this measure received by The Joint Commission which showed that some of the age strata had very low sample sizes and that a single C-section in one of these strata could adjust a hospital's observed results between 5-10 percentage points.”

However, instead of developing a new maternal age risk adjustment in 2015 that was free of fatal flaws the Joint Commission decided to make the unbelievable claim that maternal age risk adjustment is no longer required because recent studies show that hospitals with older patients have thinner patients and hospitals with younger patients have heavier patients and therefore the risk from increasing maternal age is canceled out by maternal BMI. The following is from the Joint Commission's submission to the (NQF) in 2016 (Perinatal and Reproductive Health 2015-2016, Final Report, December 16, 2016. Pages 49-50):

“The final decision to remove all risk-adjustment from this measure was made after submitting the measure to NQF and is based on evidence from two recent studies^{1,2} which have shown that hospitals with a high maternal age population also have a low body mass index (BMI) and conversely, those with low maternal age have a high BMI (at the time of the first birth).”

¹ Caceres IA, Arcaya M, Declercq E, Belanoff CM, Janakiraman V, et al. (2013) Hospital Differences in Cesarean Deliveries in Massachusetts (US) 2004–2006: The Case against Case-Mix Artifact. PLoS ONE 8(3): e57817. doi:10.1371/journal.pone.0057817 – **[DOESN'T HAVE BMI AS A RISK FACTOR]**

² Main E. (2014) Nulliparous, Term, Singleton, Vertex (NTSV) Cesarean Birth Rates: extreme hospital variation is not changed by adjustment for case-mix. Oral Presentation: Pacific Coast Obstetrics and Gynecology Society – **[NEVER PUBLISHED]**

The claim made by the Joint Commission is supported by only one published study and that study doesn't even have maternal BMI as a risk factor. The second reference was a lecture whose study has never been published. A more detailed history of this unbelievable claim can be found in our video presentations and documentation on our website www.Birthrisk.com.

The NQF requires that every measure must provide validation. However, the only validation that exists for this measure is the fact that hospitals have not provided any negative feedback questioning its validity. Below are the pertinent sections from the final NQF submission for this measure regarding validity testing and risk adjustment. We hope that in addition to improving patient care that our preliminary analysis will enable your hospital to provide feedback to the Joint Commission and to the NQF.

The following is from the National Quality Forum's (NQF) website and was retrieved on April 1, 2018. This is the information that the NQF used in 2016 to endorse measure 0471 (aka Joint Commission Core Measure PC-02:Cesarean Birth). https://www.qualityforum.org/Measures_List.aspx (Measure 0471, View the New Spec, PC-02_0471_MeasureTesting_MSF5_0_Data_UPDATED_8_23.doc)

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

2b2.2 Analytic Method (*Describe method of validity testing and rationale; if face validity, describe systematic assessment*):

Since the measure has been in national use, continued face validity of the measure has been determined through analysis of feedback from measure users. The Joint Commission provides a web-based application with which measure users can provide feedback regarding appropriateness of measure specifications, request clarification of specifications, and/or provide other comments pertinent to the measure. This feedback is systematically continually reviewed in order to identify trends and to identify areas of the measure specifications that require clarification or revision. Additionally, Joint Commission staff continually monitors the national literature and environment in order to assess continued validity of this measure.

As noted previously, The Joint Commission is currently performing reliability site visits this year. A component of these visits will include focus group interviews with hospital staff working with the PC measures to obtain feedback regarding the validity of the measures and suggestions for further refinement of the specifications.

2b4. Risk Adjustment/Stratification for outcome or resource use measures

2b4.2. If an outcome or resource use measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

After the submission of this form and before the standing committee meeting at which this measure was discussed the Joint Commission's Perinatal Care Technical Advisory Panel recommended using the simple cesarean birth rates without further risk adjustment. The decision to remove all risk-adjustment from this measure was made based on analysis of data on this measure received by The Joint Commission which showed that some of the age strata had very low sample sizes and that a single C-section in one of these strata could adjust a hospital's observed results between 5-10 percentage points. This indicates extreme sensitivity of the adjusted results to low sample sizes, indicating the directly adjusted results using age strata were not an accurate representation of the hospital's true performance. Also a preliminary analysis of the data using 2014 discharges with a logistic regression of the outcome, with the age strata as risk factors, indicated that the age strata had marginal impact on the outcome. The results of this analysis were not kept.

The combination of marginal impact of the age strata with sensitivity of the results to low sample sizes were two of the reasons for deciding to not continue to use direct stratification by age category to risk-adjust the measure.

Additionally, the Technical Advisory Panel considered evidence from two recent studies^{1, 2} when making the recommendation to remove age standardization from the measure. Therefore, effective with discharges beginning July 1, 2016, The Joint Commission has removed all risk adjustments.

¹ Caceres IA, Arcaya M, Declercq E, Belanoff CM, Janakiraman V, et al. (2013) Hospital Differences in Cesarean Deliveries in Massachusetts (US) 2004–2006: The Case against Case-Mix Artifact. PLoS ONE 8(3): e57817. doi:10.1371/journal.pone.0057817

² Main E. (2014) Nuliparous, Term, Singleton, Vertex (NTSV) Cesarean Birth Rates: extreme hospital variation is not changed by adjustment for case-mix. Oral Presentation: Pacific Coast Obstetrics and Gynecology Society

References:

1. Bailit J, Garrett J. Comparison of Risk-Adjustment Methodologies for Cesarean Delivery Rates. *Obstet Gynecol* 2003;102:45–51.
2. Bailit JL, Love TE, Mercer B. Rising cesarean rates: are patients sicker? *Am J Obstet Gynecol* 2004;191:800-3.
3. Bayrampour H, Heaman M. Advanced Maternal Age and the Risk of Cesarean Birth: A Systematic Review. *Birth* 2010;37(3):219-25
4. Bergholt T, Lim L, Jorgensen J, Robson M. Maternal body mass index in the first trimester and risk of cesarean delivery in nulliparous women in spontaneous labor. *Am J Obstet Gynecol* 2007;196(2):163.e1-5
5. Burk N, Burk G, Breathnach F, McAuliffe F, Morrison J, et al. How to predict cesarean delivery in the nulliparous patient: results from the prospective multi-center Genesis Study. *Am J Obstet Gynecol* 2016;214(1):S15
6. Chen G, Uryasev S, Young T. On prediction of the cesarean delivery risk in a large private practice. *Am J Obstet Gynecol* 2004;191:617-25
7. Cleary-Goldman J, Malone FD, Vidaver J, et al. Impact of maternal age on obstetric outcome. *Obstet Gynecol* 2005;105:983–990.
8. Coonrod DV, Drachman D, Hobson P, et al. Nulliparous term singleton vertex cesarean delivery rates: institutional and individual level predictors. *Am J Obstet Gynecol* 2008;198:694.e1-694.e11
9. Declercq E, MacDorman M, Osterman M, Belanoff C, Iverson R. Prepregnancy Obesity and Primary Cesareans among Otherwise Low-Risk Mothers in 38 U.S. States in 2012. *Birth* 2015;42(4):309-18
10. Declercq E, Menacker F, MacDorman M. Maternal risk profiles and the primary cesarean rate in the United States, 1991–2002. *Am J Public Health* 2006;96:867–872.
11. Denk CE, Kruse LK, Jain NJ. Surveillance of cesarean section deliveries, New Jersey, 1999–2004. *Birth* 2006;33:203–209.
12. Dulitzki M, Soriano D, Schiff E, et al. Effect of very advanced maternal age on pregnancy outcome and rate of cesarean delivery. *Obstet Gynecol* 1998;92:935–939.
13. Ecker JL, Chen KT, Cohen AP, et al. Increased risk of cesarean delivery with advancing maternal age: Indications and associated factors in nulliparous women. *Am J Obstet Gynecol* 2001; 185:883–887.
14. Freeman R, Cohen A, Depp R, Frigolette F, Hankins G, et. al. Evaluation of Cesarean Delivery. American College of Obstetricians and Gynecologists. Task Force on Cesarean Delivery Rates. 2000
15. Gareen IF, Morgenstern H, Greenland S, Gifford DS. Explaining the association of maternal age with cesarean delivery for nulliparous and parous women. *J Clin Epidemiol* 2003;56:1100–1110.
16. Heffner LJ, Elkin E, Fretts RC. Impact of labor induction, gestational age, and maternal age on cesarean delivery rates. *Obstet Gynecol* 2003;102:287–293.
17. Hin LY, Lau TK, Rogers M, Chang AM. Antepartum and intrapartum prediction of cesarean need: Risk scoring in singleton pregnancies. *Obstet Gynecol* 1997;90:183–186.
18. Jacobsson B, Ladfors L, Milsom I. Advanced maternal age and adverse perinatal outcome. *Obstet Gynecol* 2004;104:727–733.
19. Linton A, Peterson MR, Williams TV. Effects of maternal characteristics on cesarean delivery rates among U.S. Department of Defense healthcare beneficiaries, 1996–2002. *Birth* 2004;31:3–11.
20. Main E, Moore D, Farrel B, Schimmel L, Altman R, Abrahams C, et al. Is there a useful cesarean birth measure? Assessment of the nulliparous term singleton vertex cesarean birth rate as a tool for obstetric quality improvement. *Am J Obstet Gynecol* 2006;194:1644-52
21. Maslow A, Sweeny A. Elective Induction of Labor as a Risk Factor for Cesarean Delivery Among Low-Risk Women at Term. *Obstet & Gynecol* 2000;95:917-22
22. National Center for Health Statistics, National Vital Statistics Reports Volume 63, Number 6, Available at https://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_06.pdf. Retrieved April 1, 2018.
23. National Center for Health Statistics, National Vital Statistics Reports Volume 67, Number 1, Available at https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf. Retrieved April 1, 2018.
24. Prysak M, Lorenz RP, Kisly A. Pregnancy outcome in nulliparous women 35 years and older. *Obstet Gynecol* 1995;85:65–70.
25. Richards M, Flanagan M, Littman A, Burke A, Callegari L. Primary cesarean section and adverse delivery outcomes among women of very advanced maternal age. *Journal Of Perinatology* 2016;36:272-7
26. Tolcher M, Holbert M, Weaver A, McGree M, Olson J, El-Nashar S, et. al. Predicting Cesarean Delivery After Induction of Labor Among Nulliparous Women at Term. *Obstet Gynecol* 2015;126:1059-68
27. Treacy A, Robson M, O’Herlihy C. Dystocia increases with advancing maternal age. *Am J Obstet Gynecol* 2006;195:760–763.
28. Wilkes P, Wolf D, Kronbach D, Kunze M, Gibbs R. Risk Factors for Cesarean Delivery at Presentation of Nulliparous Patients in Labor. *Obstet Gynecol* 2003;102:1352-7

29. The table below was created using the data published by the National Vital Statistics Reports. This table represents the effect of age on the cesarean birth rate of NTSV patients in the United States over the past 20 years. It is provided so that you have some context to the Joint Commission's claim made to the National Quality Forum in 2016 that : "age strata had marginal impact on the outcome".

Year	Age					
	Under 20	20-24	25-29	30-34	35-39	40 and over
2016	16.5	21.8	25.5	29.8	38.7	52.2
2015	16.7	22.1	25.7	30.1	39.0	52.0
2014	17.4	22.6	25.9	30.4	39.4	52.7
2013	18.3	23.6	26.9	31.7	40.8	53.5
2012	19.0	24.1	27.7	32.4	41.7	53.3
2011	19.0	24.2	27.9	32.7	41.6	52.8
2010	19.3	24.6	28.4	33.5	42.6	54.3
2009	19.9	25.3	29.2	34.2	43.6	54.5
2008	19.7	24.8	28.8	34.4	43.6	54.5
2007	19.5	24.5	28.8	34.4	43.2	53.4
2006	19.1	23.9	28.1	33.8	42.9	53.6
2005	18.6	23.3	27.6	33.5	41.9	52.3
2004	17.8	22.4	26.7	32.3	40.6	50.7
2003	16.7	21.0	25.2	30.8	39.5	48.3
2002	15.5	19.9	24.3	29.5	37.8	46.9
2001	14.5	18.7	23.0	27.8	35.8	44.1
2000	13.4	17.7	21.9	26.3	34.0	42.5
1999	12.8	16.9	20.9	25.7	33.0	40.6
1998	12.3	16.3	20.3	24.7	31.7	38.9
1997	12.1	16.4	19.7	24.2	31.0	38.6

**THIS IS THE END OF THE PRELIMINARY
ANALYSIS REPORT**

The following are examples of our detailed analysis and comparison reports and are available only by subscription:

The Birthrisk Cesarean Birth Measure can easily identify which providers in your hospital are providing cesarean birth utilization that is statistically significantly worse, the same or better than the average for your hospital. If available your providers or hospital can be compared to the average in the county, state or the entire country. Please view the 47 minute video presentation on our website which provides information on the Birthrisk Cesarean Birth Measure.

Birthrisk Cesarean Birth Measure (BCBM) Report for an actual Hospital					
Total Number of Births	Actual Cesarean Birth Rate	Expected Cesarean Birth Rate	Birthrisk Cesarean Birth Measure (BCBM)		
1,003	26.33%	12.06%	27.85%		
BCBM Report for each provider					
Total number of births	Actual Cesarean Birth Rate	Expected Cesarean Birth Rate	BCBM	P Value	Provider ID
166	42.17%	11.49	46.83%	0.001	1332
88	37.50%	10.27	46.57%	0.001	389
31	48.39%	16.61	37.16%	0.3524	1133
41	36.59%	14.34	32.55%	0.6312	408
192	26.04%	11.24	29.55%	0.6966	891
39	30.77%	14.67	26.77%	1	937
55	25.45%	15.65	20.74%	0.3222	860
37	21.62%	14.08	19.59%	0.3576	3063
37	13.51%	11.14	15.48%	0.1416	2427
31	12.90%	11.55	14.25%	0.1416	644
182	14.84%	10.55	17.94%	0.007	362
58	15.52%	14.98	13.21%	0.022	3052
46	10.87%	13.17	10.53%	0.0156	1311

Hospital Comparison Report

Country: **United States** State **New York** County: **Yours**

Hospital/Facility: **9526**

This is an actual hospital in New York State (dates changed)

Note that a hospital's deliveries are removed from the County and State calculations.

First Time Mothers	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Starting Date	1/1/2017	1/1/2017	1/1/2017
Ending Date	12/31/2017	12/31/2017	12/31/2017
Number of patients	465	305	160
Hospital Cesarean Birth Rate	38.71	31.48	52.50
Expected cesarean birth rate	21.17	16.29	30.48
Hospital Birthrisk Cesarean Birth Measure	41.83	35.75	56.92
County Birthrisk Cesarean Birth Measure*	25.70	20.70	37.35
State Birthrisk Cesarean Birth Measure*	25.70	20.70	37.35

Previous Vaginal Birth	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Starting Date	1/1/2017	1/1/2017	1/1/2017
Ending Date	12/31/2017	12/31/2017	12/31/2017
Number of patients	549	425	124
Hospital Cesarean Delivery Rate	15.85	12.71	26.61
Expected cesarean birth rate	4.34	3.75	6.38
Hospital Birthrisk Cesarean Birth Measure	15.93	12.60	26.28
County Birthrisk Cesarean Birth Measure*	4.86	3.87	7.80
State Birthrisk Cesarean Birth Measure*	4.86	3.87	7.80

Measure, Compare and Improve.

* County and State comparisons will only be available if other entities are submitting data

Obstetrical Care Provider Comparison Report

Country: **United States** State **New York** County: **Yours**

Hospital/Facility: **9526** Obstetrical Group: **3331356512**

This is an actual obstetrical care provider in New York State (dates changes)

Note that a provider's deliveries are removed from the Hospital, County and State calculations.

First Time Mothers	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Starting Date	1/1/2017	1/1/2017	1/1/2017
Ending Date	12/31/2017	12/31/2017	12/31/2017
Number of patients	77	55	22
Obstetrical care provider cesarean birth rate	40.26	38.18	45.45
Expected cesarean birth rate	21.73	17.38	32.59
Provider Birthrisk Cesarean Birth Measure	42.40	40.65	46.08
Hospital Birthrisk Cesarean Birth Measure	41.72	34.59	58.79

Previous Vaginal Birth	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Starting Date	1/1/2017	1/1/2017	1/1/2017
Ending Date	12/31/2017	12/31/2017	12/31/2017
Number of patients	115	93	22
Obstetrical care provider cesarean birth rate	16.52	11.83	36.36
Expected cesarean birth rate	4.23	3.62	6.77
Provider Birthrisk Cesarean Birth Measure	17.08	12.14	33.82
Hospital Birthrisk Cesarean Birth Measure	15.64	12.72	24.52

Detailed Nulliparous Comparison Report

Country: **United States** State **New York** County: **Yours**

Hospital/Facility: **9526** Obstetrical Group: **3331356512**

Note that your group's births are removed from the Hospital, County and State calculations.

This report is restricted to: Prior Vaginal Births: **No** Date Range: **1/1/2017 - 12/31/2017**

	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Number of patients for your Group	77	55	22
Percent of vaginal births assisted by forceps	0.00	0.00	0.00
Percent of vaginal births assisted by vacuum	0.00	0.00	0.00
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
Your Cesarean Birth Rate	40.26	38.18	45.45
Your Expected Cesarean Birth Rate	21.73	17.38	32.59
Your Birthrisk Cesarean Birth Measure	42.40	40.65	46.08
Number of patients for Hospital	388	250	138
Percent of vaginal births assisted by forceps	0.00	0.00	0.00
Percent of vaginal births assisted by vacuum	10.04	8.00	15.63
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
Hospital Cesarean Birth Rate	38.40	30.00	53.62
Hospital Expected Cesarean Birth Rate	21.06	16.05	30.14
Hospital Birthrisk Cesarean Birth Measure	41.72	34.59	58.79
Number of patients for County	33,036	23,091	9,945
Percent of vaginal births assisted by forceps	1.20	1.10	1.47
Percent of vaginal births assisted by vacuum	8.12	7.49	9.95
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
County Cesarean Birth Rate	25.85	20.80	37.58
County Expected Cesarean Birth Rate	22.88	18.51	33.04
County Birthrisk Cesarean Birth Measure	25.85	20.80	37.58

Detailed Multiparous Comparison Report

Country: **United States** State **New York** County: **Yours**

Hospital/Facility: **9526** Obstetrical Group: **3331356512**

Note that your group's births are removed from the Hospital, County and State calculations.
This report is restricted to: Prior Vaginal Birth: **Yes** Date Range: **1/1/2017 - 12/31/2017**

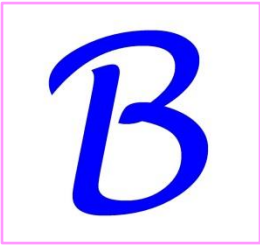
	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Number of patients for your Group	115	93	22
Percent of vaginal births assisted by forceps	0.00	0.00	0.00
Percent of vaginal births assisted by vacuum	2.08	0.00	14.29
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
Your Cesarean Birth Rate	16.52	11.83	36.36
Your Expected Cesarean Birth Rate	4.23	3.62	6.77
Your Birthrisk Cesarean Birth Measure	17.08	12.14	33.82
Number of patients for Hospital	434	332	102
Percent of vaginal births assisted by forceps	0.00	0.00	0.00
Percent of vaginal births assisted by vacuum	0.55	0.35	1.30
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
Hospital Cesarean Birth Rate	15.67	12.95	24.51
Hospital Expected Cesarean Birth Rate	4.38	3.79	6.29
Hospital Birthrisk Cesarean Birth Measure	15.64	12.72	24.52
Number of patients for County	36,789	27,526	9,263
Percent of vaginal births assisted by forceps	0.26	0.22	0.40
Percent of vaginal births assisted by vacuum	2.05	1.85	2.64
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
County Cesarean Birth Rate	4.99	3.98	7.99
County Expected Cesarean Birth Rate	4.37	3.72	6.30
County Birthrisk Cesarean Birth Measure	4.99	3.98	7.99

Custom Detailed Nulliparous Comparison Report

State **New York** County: **Yours** Hospital/Facility: **9526** Obstetrical Group: **3331356512**
 Note that your group's births are removed from the Hospital, County and State calculations. This report is restricted to: Prior Vaginal Birth: **No** Date Range: **1/1/2017 - 12/31/2017**

Maternal Height restricted to: **65 in - 84 in**

	Both Spontaneous & Induced	Spontaneous Only	Induced Only
Number of patients for your Group	18	12	6
Percent of vaginal births assisted by forceps	0.00	0.00	0.00
Percent of vaginal births assisted by vacuum	0.00	0.00	0.00
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
Your Cesarean Birth Rate	50.00	50.00	50.00
Your Expected Cesarean Birth Rate	21.33	17.25	29.50
Your Birthrisk Cesarean Birth Measure	46.87	45.07	50.39
Number of patients for Hospital	135	90	45
Percent of vaginal births assisted by forceps	0.00	0.00	0.00
Percent of vaginal births assisted by vacuum	11.76	9.09	21.05
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
Hospital Cesarean Birth Rate	37.04	26.67	57.78
Hospital Expected Cesarean Birth Rate	18.04	13.64	26.84
Hospital Birthrisk Cesarean Birth Measure	41.05	30.38	63.98
Number of patients for County	14,302	9,813	4,489
Percent of vaginal births assisted by forceps	1.13	1.06	1.33
Percent of vaginal births assisted by vacuum	7.55	6.95	9.20
Percent of patients with a complete Bishop score	0.00	0.00	0.00
Average Bishop score	0.00	0.00	0.00
County Cesarean Birth Rate	22.16	17.25	32.90
County Expected Cesarean Birth Rate	20.00	15.55	29.73
County Birthrisk Cesarean Birth Measure	22.16	17.25	32.90



Quality Improvement vs. Research

Using our software tools is considered by Birthrisk.com, LLC as a Quality Improvement (QI) process which is a part of your entity's routine health care operations. However, our tools have been developed with guidance from both the Office of Human Research Protection (OHRP) and the Federal Drug Administration in an effort to comply with all regulations for use in research as well.

The Hastings Center convened leaders and scholars to address the ethical requirements for QI and their relationship to regulations protecting human subjects of research (1). The group defined QI as "systemic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings."

The OHRP defines research in 45 Code of Federal Regulations (CFR) 46.102(d) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The tools at Birthrisk.com use an established quality improvement method (Plan-Do-Study-Act cycle) aimed at producing change only within the health care entity. However, our tools could be used in research. As with any other research, the use of our tools in research would require Institutional Review Board (IRB) approval. We strongly recommend that all research activity also be reviewed with Birthrisk.com, LLC in order to ensure that the intended study design is consistent with the capabilities of our tools.

The data used by our tools do not contain any direct patient identifiers as defined in The Privacy Rule and therefore qualifies as a limited data set of Protected Health Information (PHI). The Privacy Rule states that "A covered entity may use and disclose a limited data set for research activities conducted by itself, another covered entity, or a researcher who is not a covered entity if the disclosing covered entity and the limited data set recipient enter into a data use agreement. Limited data sets may be used or disclosed only for purposes of research, public health, or health care operations."

A data use agreement is required by The Privacy Rule and will be executed with your health care entity. If you have any question as to whether your intended use of our tools is QI or research please refer the matter to your local IRB.

Birthrisk.com, LLC.

1. Lynn J, Baily M, Bottrell M, Jennings B, Levine R, Davidoff F, et al. The Ethics of Using Quality Improvement Methods in Health Care. *Ann Intern Med.* 2007;146:666-673.