Draft Opioid Prescribing Guidelines for Uncomplicated Normal Spontaneous Vaginal Birth

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Short title: New Guidelines for Opioid Prescribing

Precis: New draft opioid-prescribing data for U.S. hospitals and draft guidelines were developed for informing opioid prescribing in uncomplicated normal spontaneous vaginal delivery.

45 **Abstract:**

46 Women who experience an uncomplicated vaginal delivery have acute intrapartum pain and variable pain in the immediate postpartum period. While the Centers for Disease Control and Prevention (CDC) has urged clinicians to improve opioid-prescribing behavior, there are no published clinical practice guidelines for prescribing opioids during labor and delivery and at discharge for patients with an uncomplicated normal spontaneous vaginal delivery . To address the knowledge gap regarding guidelines for pain management in this population, we used the national Premiere Health Care Database for deliveries of uncomplicated vaginal births from January 1, 2014 through December 31, 2016 to determine the prevalence of opioid administration. Among the 49,133 women who met inclusion criteria, 78.2% were administered opioids during hospitalization and 29.8% were administered opioids on the day of discharge. Descriptive statistics were generated to document the characteristics of the patients receiving opioids as well as the characteristics of hospitals administering opioids during inpatient labor and delivery and upon discharge. Patient level variables included age group, marital status, race, ethnicity, payer type, and length of stay. Hospital level variables included bed size, geographic region, teaching status, and urbanicity status. These data were then presented in an electronic Delphi survey to 14 participants. The survey participants were Obstetrician-Gynecologists identified by the American College of Obstetricians and Gynecologists as being thought leaders in the Obstetrics field and who had also demonstrated an active interest in the opioid epidemic and its impact on women's health. After the panelists viewed the opioid administration data, they were presented with an adapted version of the CDC's guidelines for opioid prescribing for chronic pain management. The 8 adapted guidelines were constructed to be more relevant and appropriate for the inpatient NSVD population. After three rounds of the surveying process, 7 of the 8 adapted guidelines were endorsed by the survey participants. These 7 draft consensus guidelines could now be used as a starting point to develop more broadly endorsed and studied guidelines for appropriately managing pain control for women with uncomplicated spontaneous vaginal birth.

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66 **Background:**

67 Opioid-related deaths are rising in the U.S. and contribute to 66% of drug overdose deaths and government agency and organizational leaders are looking for opportunities to employ primary, secondary, and tertiary prevention strategies.[1,2] For clinical leaders who have administrative responsibilities across multiple healthcare systems , implementing these strategies might be complicated by the substantial variation in opioid prescribing patterns.. These variations in opioid prescribing do not correlate with patient acuity and pain levels; and providers in the highest opioid prescribing U.S. states write three times the prescriptions for opioids as prescribers in the lowest opioid prescribing states.[3,4] Providers in both inpatient and outpatient settings might unknowingly contribute to high prescribing rates due to a lack of awareness about their own prescribing patterns compared to their peers. Recent national public opinion data show U.S. citizens place the majority of responsibility for the growing opioid epidemic on inappropriate physician prescribing, even though there are several significant contributing factors to the epidemic.[5]

68 Thought leaders in public health policy have called for a more comprehensive review of opioid prescribing to include the inpatient setting and have reiterated that opioid exposure avoidance is critical in prevention efforts.[7–9] The literature points to the significance of receiving an opioid as an inpatient and what this initiation portends for continued prescribing post discharge. In opioid naïve patients (patients who have not been exposed to an opioid), opioid receipt at hospital discharge is associated with an increase future chronic opioid use.[10,11]

69 When considering inpatient populations that might be targeted for reducing opioid exposure, the normal spontaneous vaginal delivery population is a strong contender for several reasons. First, labor and delivery is the most common reason for hospitalization and therefore has a significant impact on pharmacy supply, demand,

and diversion. Second, a subset of this population, patients with a normal spontaneous vaginal delivery without complications, are more homogenous in their presentation and treatment than other patient groups since they are more similar in age, presentation, and outcomes relative to diagnosis codes. Third, improving the health of mothers, infants and children is a federal priority and one of the U.S. public health goals.[12]

Child birth is typically associated with acute pain, and while some opioid use may be appropriate, other pharmacologic approaches could be considered in low risk, straightforward procedures such as uncomplicated normal spontaneous vaginal delivery. The American College of Obstetricians and Gynecologists (ACOG) has stated that pain management during delivery is appropriate, and providers should consider both pharmacologic and non-pharmacologic interventions. However, there is no direct guidance for inpatient opioid orders in the normal spontaneous vaginal delivery population, likely because there have been no national data describing the prevalence of opioid prescribing in this population. The most relevant guidance is a 2017 ACOG committee opinion based on fourteen-year-old data stating, "in the hospital setting, pharmacologic analgesia should be available for all women in labor who desire medication."[13]

The objectives of this study were twofold: 1) to describe the prevalence of opioid administration in the uncomplicated normal spontaneous vaginal delivery population; 2) to provide these data to a panel of OB-GYN physicians to inform draft opioid prescribing recommendations in the uncomplicated normal spontaneous vaginal delivery patient population. The findings from this study may help create awareness of opioid prescribing in the normal spontaneous vaginal delivery population, and encourage a larger and more diverse stakeholder group to develop a comprehensive set of guidelines that could be used for opioid prescribing for women during labor and delivery and at postpartum discharge.

Methods:

This study analyzed epidemiological data from the Premier Healthcare Database which contains hospital

reported administrative data and are de-identified in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules. These data include more than 768 million patient encounters (approximately 1 in 5 U.S. discharges) from over 760 U.S. hospitals and comprise inpatient and hospital–based outpatient encounters from all payers including Medicaid, and have been used for research purposes by academia, pharmaceutical companies, and federal agencies including the CMS, FDA, and NIH.[14]

70 This study explored hospital- and patient- level characteristics for patients with a normal spontaneous vaginal delivery who were administered opioids by any route at any point during their stay compared to those patients with a normal spontaneous vaginal delivery who were not administered an opioid. The study also investigated the characteristics of women who were administered an opioid by any route in the hospital on the day of discharge compared to those who were not. Inclusion criteria included admitted women aged 15-44 years who had a delivery hospitalization including a normal spontaneous vaginal delivery from January 1, 2014 through December 31, 2016 based on an ICD-9 code of 650 or an ICD-10 code of O80, as determined by hospital charge master data. Exclusion criteria were aimed at achieving the most uncomplicated normal spontaneous vaginal delivery patient population. For a full description of exclusion criteria and the final study population see the online-only material, Appendixes 1 and 2, available online at http://links.lww.com/xxx.

71 The prevalence of patients receiving opioids at any point during their hospitalization and upon discharge was calculated. Descriptive statistics were generated to document the characteristics of the patients receiving opioids during their inpatient labor and delivery visit or upon discharge. Patient level variables included age group, marital status, race, ethnicity, payer type, and length of stay. Hospital level variables included bed size, geographic region, teaching status, and urbanicity status, as defined by the U.S. Census. For a full listing of patient and hospital variables for each patient discharge with opioid administration see the online-only material, Appendix 3 available online at http://links.lww.com/xxx .

72 Bivariate analysis was used to determine predictors of opioid administration at each time point. Chi-square

tests were used to test for statistical differences between patients with a normal spontaneous vaginal delivery administered opioids versus those who were not. Covariates with a p-value of 0.10 or less were entered into a multilevel, multivariate logistic regression model using generalized linear mixed-effects modeling (GLMM). GLMM was used to estimate the adjusted odds of the patient receiving an opioid (at any point during visit/upon discharge) and to account for the clustering of patients within hospitals as well as for the non-normal distributions of dependent data.

These data were summarized and presented to a panel of OB-GYN physician leaders who were invited to participate in an e-Delphi panel for three rounds of surveying from December 2017 through February 2018. The purpose of the panel was to provide consensus on eight draft recommendations for opioid prescribing guidelines for labor and delivery and on the day of discharge for normal spontaneous vaginal delivery without complications.

73 The Delphi technique was chosen because it is a consensus building technique with a fifty-year history as an appropriate method for assimilating and integrating opinions from panelists who have in-depth knowledge within a given topic.[15] The advantages of the technique include panelist anonymity, and a statistical group response from an iterative process with controlled feedback.[16] Because questions were submitted to the Delphi panel electronically and responses were also gathered electronically, this study utilized what has been referred to as the e-Delphi approach which has been employed in other healthcare policy and practice research.[17-24]

The protocol required that all e-Delphi participants held a current MD or DO license; selection was based on participants' ability to bring clinical knowledge and leadership experience to the research question. The panel comprised fourteen participants (Appendix 4 for panel participants and credentials, available online at http://links.lww.com/xxx). Fifteen has been suggested as an ideal panel number though larger panels are

recommended for multiple stakeholder groups.[25] This panel size was chosen because the participants were homogenous in their expertise and literature suggests that size of the panel should correlate to goals of the panel and the homogeneity needed.[25-27] Homogeneity was important in this instance because the investigators wanted to provide an initial set of recommendations from a key prescribing stakeholder group in a timely manner. The intent was for the draft recommendations to be used as a starting point for deeper dialogue and to inform subsequent final guidelines which represent multiple viewpoints and experiences from various stakeholders.

74 The physician panelists were selected by the principal investigator (PI) after contacting ACOG for the names of MDs and DOs who were considered leaders in the Obstetrics field and had demonstrated an active interest in the opioid epidemic and the impact on women's health. From this group the final cohort of panelists was selected basedon the following criteria:

137 - Informed consent and willingness to participate in two to three rounds of
138 consensus building over the span of 2-3 months;
139 - Currently or previously served as a leader or practitioner in
140 obstetrics and gynecology. Leader was defined as having influence in
141 academic institutions, medical societies or policy groups and serving in a
142 role to use that influence to affect change in the healthcare system.
143 - Interest in opioid prescribing and substance abuse or opioid use disorder
144 (OUD), which was verified in the form of serving on professional
145 committees, public speaking or other professional endeavors;
146 - Willingness to revise initial responses in an effort to reach
147 consensus.[15]

The e-Delphi panelists were presented a summary of the national data which described opioid administration prevalence in patients with an uncomplicated normal spontaneous vaginal delivery in U.S. hospitals. The panelists were then individually surveyed to assess their respective agreement regarding each of the eight drafted guidelines. Survey question composition was quantitative in nature with an opportunity for qualitative input following review of each of the eight proposed guidelines. The quantitative answers were expressed via a Likert scale with measures of central tendency reported.[15] There is no standard guideline for defining consensus when using the Delphi technique; researchers have used multiple approaches including interquartile ranges (IQRs) and median scores.[28,29] Using a four-point Likert scale, consensus was met for each guideline if the majority of Delphi participants rated the guideline with a three or higher, with a median of 3.25 or higher, and the IQR was 1 or less.[30,31] The consensus threshold was established prior to convening the e-Delphi panel.

Before each survey round commenced, a survey link was emailed to participants with instructions for completion and return. All respondents received an individual code that only the PI and respondent knew; all data were password protected and stored electronically.

The protocol stated that if consensus was not obtained in the first survey round, another round would be added, but there would be no more than three survey rounds. The rationale for limiting the survey to three rounds was based on guidance provided in the literature.[32]

The first round of survey questions was based on the opioid administration prevalence data and the adapted CDC guidelines.[33] The questions were submitted to the de-identified panelists via a commercially available survey tool, Survey Monkey. The primary purpose of this round was to identify priority areas for formulating recommendations on opioid prescribing practices during labor and delivery for patients with an uncomplicated normal spontaneous vaginal delivery and to respond to the suggested adaptation of the

CDC guidelines for prescribing opioids to patients with an uncomplicated normal spontaneous vaginal delivery. The patient population was defined as patients with normal spontaneous vaginal delivery without delivery complications (complications included tubal ligation, patients with a contraindication to NSAIDs, patients undergoing cesarean delivery, deliveries with fetal

159 distress, episiotomy, use of forceps, vacuum, assisted delivery, any level of laceration. For a full list of complications see Appendix 1 (http://links.lww.com/xxx), which lists all exclusions by ICD-9 or ICD-10 or HCPCS codes). Two subsequent rounds of surveying were used to refine the recommendations which did not achieve consensus. See Figure 1 for a depiction of the e-Delphi process. Institutional Review Board (IRB) approval for this project was secured through the University of Illinois, Chicago.

160 **Results:**

161 The data presented to the panel showed the population of interest comprised 106,518 patients with a normal spontaneous vaginal delivery. After applying the exclusionary criteria, there were 49,133 (46.13%) patients remaining with an uncomplicated normal spontaneous vaginal delivery.

162 Among patients with an uncomplicated normal spontaneous vaginal delivery, 38, 432 (78.2%) received an opioid at some point during their hospitalization and 14, 635 (29.8%) received an opioid on the day of discharge (Table 1). Tables 2 and 3 provide the adjusted odds ratios for the relationship between patient and hospital characteristics and the likelihood of receiving an opioid during hospitalization (Table 2) and the likelihood of receiving an opioid on the day of discharge (Table 3). The odds for a black patient being administered an opioid during hospitalization were 42% higher than the odds for a white patient (adjusted odds ratio 1.42 {95% CI 1.31-1.54}) The odds for a Medicaid patient being administered an opioid during hospitalization were 36% higher than the odds for a commercially insured patient (adjusted odds ratio 1.36 {95% CI 1.21-1.51}). The odds for a patient being administered an opioid at a teaching hospital were 20% lower than the odds for patients in a non-

teaching facility adjusted odds ratio 0.80 {95% CI 0.65-0.99}).

163 Regarding the routes of administration and the trends of utilization during hospitalization, there was little change year over year. For opioid data by route of administration during hospitalization over the three years, see the online-only material, Appendix 5, available online at http://links.lww.com/xxx.

The e-Delphi panelists reviewed these data prior to participating in the survey rounds. After the first round of surveying, five of the eight draft guidelines had achieved consensus by the panel. In the second and third rounds of surveying, one additional draft guideline had reached consensus in each round resulting in seven of the eight draft guidelines achieving consensus. All fourteen panelists participated in all three rounds of surveying and scored each adapted guideline for every round of surveying, resulting in zero attrition and a 100% response rate during three months of surveys.

The draft guidelines reaching consensus in the first round were:

G1: Long-term opioid use often begins with the treatment of acute pain. When opioids are started, clinicians should order the lowest effective dosage and prescribe no greater quantity of opioids than needed for the expected duration of such pain severe enough to require opioids.

G2: When starting opioid therapy, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids. This is especially important on the day of discharge.

G3: Clinicians should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible.

G5: Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for normal spontaneous vaginal delivery patients with no complications. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

G7: When clinicians identify a patient with Opioid Use Disorder or OUD, treatment discussions should be prioritized during hospitalization, upon discharge and at the postpartum appointment.

After the second round of surveying Guideline 6 reached consensus: Clinicians and hospital administration should consider implementing a protocol for opioid prescribing for patients with an uncomplicated normal spontaneous vaginal delivery during and after delivery. This could help prevent opioid orders becoming routine in patients with an uncomplicated normal spontaneous vaginal delivery where the benefit may not outweigh the risk for mother and fetus. After the third round of surveying Guideline 4 achieved consensus:

Guideline 4: Options and expectations for intra- and post-partum pain management should be an essential component of every patient's care and be customized to each woman's needs and history. It is recommended that clinicians address these options with their patients as part of the labor and birth goals discussion. The clinician should document that pain management options were discussed, questions answered, and the patient appeared to understand.

Guideline 8 did not achieve consensus after three e-Delphi rounds.

Guideline 8: Clinicians should review the patient's history of controlled substance use. If the clinician determines the patient is utilizing opioids (prescribed or unprescribed), the clinician should work with pain management personnel to develop a plan for intra- and post-partum pain medication. A prenatal consult with neonatology or a pediatrician, to counsel the patient about the risk for Neonatal Abstinence Syndrome, should be strongly advised.

See Table 4 for the level of consensus achieved for each guideline.

Discussion:

During any procedure, a patient's perception of pain and their corresponding response will differ. It is also understood that different procedures will require differing levels of intervention and likely impact the level of

pain a patient may experience. Hence, there is an understanding in the medical community that uncomplicated vaginal births should, in most cases, require a different pain management approach than complicated births. Patients with an uncomplicated normal spontaneous vaginal delivery are an appropriate population to consider as healthcare leadership in the inpatient setting seek to provide clinical guidance for opioid prescribing in non-surgical populations. These data are timely given that prescribers and hospital organizations are looking for ways to diagnose and evaluate their own systems of care relative to their respective roles in reducing the prevalence of opioid prescribing, abuse, overdose and diversion. Until now, prevalence data regarding opioid administration in the normal spontaneous vaginal delivery population has not been available and this is likely why there has been no perceived need for national pain management guidelines related to opioid administration during normal spontaneous vaginal delivery procedures.

Regardless of differing and distinguishing delivery characteristics, there are no published clinical guidelines for pain management and narcotic use relative to complicated vs. uncomplicated births.[34] This study provides the prevalence data for opioid administration during hospitalization and on the day of discharge for patients with an uncomplicated normal spontaneous vaginal delivery. The seven proposed guidelines in Table 4 could serve as a starting point for obstetric health clinicians as they consider practical ways to limit opioid exposure for their patients.

166 It is worth considering that while consensus was not achieved for Guideline 8, it received considerable qualitative commentary. Based on the comments and divergent scoring, it is likely that consensus would still not have been reached even with additional rounds of surveying. The qualitative commentary showed that where there was validation of this guideline, it came from panelists who wanted more support and accountability for providers, and from panelists who believed that opioid use should be treated as a medical condition.

167 Panelists commented that pain management personnel and neonatologists should be consulted

168 regarding opioid use because of its impact on the approach providers use to care for both the
169 mother and baby. Those panelists who dissented commented that this guideline places an onerous burden on the physician and is unrealistic. They noted that in some communities, it may not be feasible to involve other clinicians to counsel the patient on neonatal abstinence syndrome (NAS) and other risks associated with opioid utilization.

48 The data from this study may encourage leaders in clinical practice and hospital administration to consider their own prescribing data relative to their organizations' respective formularies, protocols, policies and prescribing disciplines for this class of drugs. Similar approaches may be considered for the complicated normal spontaneous vaginal delivery and cesarean delivery populations.

49 These draft recommendations informed by national data on current opioid prescribing for patients with an uncomplicated normal spontaneous vaginal delivery might reduce unnecessary exposure to opioids in maternal and newborn populations and reduce the opportunity for opioid diversion. Leaders in public health policy, clinical practice, and hospital administration have an opportunity to further revise and deploy these newly developed draft recommendations in the advancement of prevention efforts to address the U.S. opioid crisis.

There are several limitations to this study. With regard to the generalizability of these results, comparisons of hospital characteristics between the hospitals submitting data to Premier Healthcare Database and the 2016 member hospitals of the American Hospital Association (AHA) are similar in distribution, although the AHA has a greater number of smaller hospitals.[14] Also, this study uses administrative data which comes from U.S. hospitals and is based on charge master data, thus including only aspects of care for which the patient was charged and not necessarily everything the patient received.

170 There were also limitations with regard to panel composition. The panel was not heterogenous and it was comprised of physicians only; midwives and other clinicians were not represented. Further, the panelists were

mostly located on the East Coast with strong affiliations with academic medical centers in an urban setting.

Additionally, these draft guidelines are specifically for patients with an uncomplicated normal spontaneous vaginal delivery, yet, during the e-Delphi process, a few of the panelists questioned what should be done when there are lacerations, episiotomies or other complications. Although these exclusions were highlighted in the instructions, it may be that some panelists thought they were voting on normal spontaneous vaginal delivery guidelines in general versus guidelines for the least complicated normal spontaneous vaginal delivery deliveries.

Finally, though the e-Delphi technique is a well-documented consensus building approach, the advantage of the anonymity of this approach also poses a limitation as the study uses an electronic platform. The panelists affirmed in writing that their respective answers are their own, but this assurance is not the same as interviewing or surveying participants in person. A more robust and cohesive set of recommendations may have been achieved if the process for consensus building had been conducted in a live versus online format, and originated from the panelists themselves vs. being adapted from the CDC guidelines.

On a national level, the U.S. Department of Health and Human Services Office for Women's Health has called all stakeholders to "foster a national conversation on best practices to prevent, diagnose and treat opioid-related hazards and death among women."[8] These data show the prevalence of opioid administration in the least complicated normal spontaneous vaginal delivery population and that both patient and hospital characteristics may have an important impact on opioid administration. As clinical and administrative leaders look for additional ways to prevent abuse, overdose and death related to opioids, these data and draft guidelines may provide a starting point for discussions regarding local and national opioid prescribing guidelines for inpatient populations such as patients with an uncomplicated normal spontaneous vaginal delivery. Actionable recommendations based on this data may serve to springboard the work for which the OWH, the CDC, ACOG and others are calling.

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Table 1: Prevalence of Opioid Administration for Patients With a Normal Spontaneous Vaginal Delivery During Hospitalization and on Day of Discharge (January 1, 2014 - December 31, 2016)

Dis-charge Year	Number of Patients	NSVD Encounters with Opioid Administration During Hospitalization (any route) (n, %)	NSVD Encounters with No Opioid Administration During Hospitalization (any route) (n, %)	NSVD Encounters with Opioid Administration on Day of Discharge (any route) (n, %)	NSVD Encounters with No Opioid Administration on Day of Discharge (any route) (n %)
2014	17,357	13,575 (78.2%)	3,782 (21.8%)	5,291 (30.5%)	12,066 (69.5%)
2015	17,188	13,532 (78.7%)	3,656 (21.3%)	5,238 (30.5%)	11,950 (69.5%)
2016	14,588	11,325 (77.6%)	3,263 (22.4%)	4,106 (28.1%)	10,482 (71.9%)
Total	49,133	N= 38,432 (78.2%)	N= 10,701 (21.8%)	N= 14,635 (29.8%)	N= 34,498 (70.2%)

Key: NSVD: normal spontaneous vaginal delivery

Table 2. Percents, and Adjusted Odds Ratios for the Relationship between Patient and Hospital Characteristics and the Receipt of an Opioid During Hospitalization for Patients with a Normal Spontaneous Vaginal Delivery (January 1, 2014 - December 31, 2016)

Effects	Description	% of Patients Administered Opioid During Hospitalization	Adjusted Odds Ratio	95% Wald Lower Confidence	95% Wald Upper Confidence
Age	19-34 (ref 15-18)	78.16	0.93	0.81	1.07
	35-44 (ref 15-18)	70.51	0.73	0.59	0.89
Marital Status	Married (ref Single)	74.62	0.68	0.64	0.72
	Other-Unknown status (ref Single)	70.50	0.79	0.70	0.89
Race	Black (ref White)	85.41	1.42	1.31	1.54
	Other (ref White)	73.56	0.92	0.86	0.97
Payor	Managed Care (ref Commercial - Indemnity)	74.34	1.07	0.96	1.21
	Medicaid (ref	81.11	1.36	1.21	1.51

	Commercial - Indemnity)				
	Other Payor (ref Commercial - Indemnity)	76.93	1.04	0.91	1.19
Hospital Geographic Region	East North Central (ref West South Central)	72.01	0.46	0.32	0.66
	East South Central (ref West South Central)	85.20	1.10	0.71	1.71
	Middle Atlantic (ref West South Central)	57.49	0.30	0.20	0.46
	Mountain (ref West South Central)	83.50	0.80	0.51	1.24
	New England (ref West South Central)	62.65	0.34	0.19	0.62

	Pacific (ref West South Central)	75.12	0.52	0.38	0.73
	South Atlantic (ref West South Central)	82.83	0.78	0.58	1.05
	West North Central (ref West South Central)	81.71	1.06	0.63	1.78
Hospital Teaching Status	Teaching (ref Non-Teaching)	73.93	0.80	0.65	0.99

Key: ref: reference group

Note: All variables in Table 3 were adjusted for all other variables in Table 3.

Table 3: Percentages and Adjusted Odds Ratios for the Relationship between Patient and Hospital Characteristics and the Receipt of an Opioid on the Day of Discharge for Patients with a Normal Spontaneous Vaginal Delivery (January 1, 2014- December 31, 2016)

Effects	Description	% of Patients Administered an Opioid on Day of Discharge	Adjusted Odds Ratio	95% Wald Lower Confidence	95% Wald Upper Confidence
Age	19-34 (ref 15-18)	30.11	1.65	1.46	1.86
	35-44 (ref 15-18)	21.84	1.27	1.04	1.54
Marital Status	Married (ref Single)	25.58	0.77	0.73	0.81
	Other-Unknown status (ref Single)	24.35	0.90	0.80	1.00
Race	Black (ref White)	39.15	1.27	1.19	1.36
	Other (ref White)	24.74	0.86	0.81	0.92
Ethnicity	Hispanic (ref non-Hispanic)	25.54	0.86	0.81	0.92
Payor	Managed Care (ref	23.98	1.10	0.98	1.23

	Commercial - Indemnity)				
	Medicaid (ref Commercial - Indemnity)	34.04	1.71	1.53	1.90
	Other Payor (ref Commercial - Indemnity)	25.72	1.22	1.07	1.40
Hospital Geographic Region	East North Central (ref West South Central)	23.86	0.44	0.32	0.60
	East South Central (ref West South Central)	38.92	0.83	0.57	1.21
	Middle Atlantic (ref West South Central)	13.55	0.24	0.17	0.36
	Mountain (ref West South Central)	32.39	0.65	0.44	0.96
	New England (ref West South Central)	12.45	0.19	0.11	0.33
	Pacific (ref West South Central)	27.15	0.57	0.43	0.77

	South Atlantic (ref West South Central)	32.11	0.62	0.48	0.80
	West North Central (ref West South Central)	34.44	0.94	0.60	1.46
Hospital Teaching Status	Teaching (ref Non-teaching)	25.54	0.79	0.65	0.95

Key: ref: reference group

Note: All variables in Table 4 were adjusted for all other variables in Table 4.

335 **Table 4: Final Recommendations and Associated Consensus Status in Each Round of e-Delphi**

336 **Surveying**

Guideline (G)	Recommendation	Consensus Yes/No	Median	Respondents Scoring a 3 or above (%)	IQR
G1	Long-term opioid use often begins with the treatment of acute pain. When opioids are started, clinicians should order the lowest effective dosage and prescribe no greater quantity of opioids than needed for the expected duration of such pain severe enough to require opioids.	**Yes**	**4**	100	.25
G2	When starting opioid therapy, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids. This is especially important on the day of discharge.	**Yes**	**4**	92.9	1
G3	Clinicians should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible.	**Yes**	**4**	92.9	1

G4	Options and expectations for intra- and post-partum pain management should be an essential component of every patient's care and be customized to each woman's needs and history. It is recommended that clinicians address these options with their patients as part of the labor and birth goals discussion. The clinician should document that pain management options were discussed, questions answered, and the patient appeared to understand.	**Yes**	4	85.7	1
G5	Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for normal spontaneous vaginal delivery patients with no complications. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.	**Yes**	**3.5**	**92.9**	1.0

G6	Clinicians and hospital administration should consider implementing a protocol for opioid prescribing for patients with an uncomplicated normal spontaneous vaginal delivery during and after delivery. This could help prevent opioid orders becoming routine in patients with an uncomplicated normal spontaneous vaginal delivery where the	**Yes**	3.5	**85.7**	1

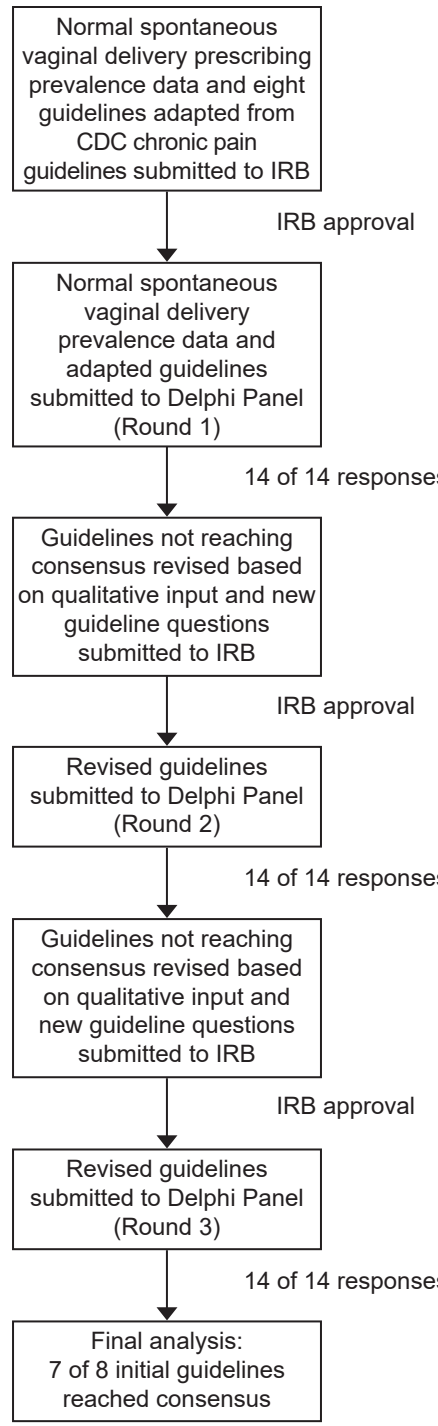
	benefit may not outweigh the risk for mother and fetus.				
G 7	When clinicians identify a patient with Opioid Use Disorder or OUD, treatment discussions should be prioritized during hospitalization, upon discharge and at the postpartum appointment.	**Yes**	3.5	**85.7**	1
G 8	Clinicians should review the patient's history of controlled substance use. If the clinician determines the patient is utilizing opioids (prescribed or unprescribed), the clinician should work with pain management personnel to develop a plan for intra- and post-partum pain medication. A prenatal consult with a neonatologist or a pediatrician, to counsel the patient about the risk for Neonatal Abstinence Syndrome, should be strongly advised.	**No**	3.0	**85.7**	1

335 Guidelines are ranked first by Median Score, then by % of Panelists Scoring 3 or above on a 4 Point Likert Scale and lastly by IQR.

606 336 **Key:** NSVD normal spontaneous vaginal delivery
607

Figure 1: Institutional review board (IRB) and Delphi Process for Consensus-Based Guidelines (October 2017–February 2018). CDC, Centers for Disease Control and Prevention.

337


Normal spontaneous vaginal delivery prescribing prevalence data and eight guidelines adapted from CDC chronic pain guidelines submitted to IRB
IRB approval
Normal spontaneous vaginal delivery prevalence data and adapted guidelines submitted to Delphi Panel (Round 1)
14 of 14 responses
Guidelines not reaching consensus revised based on qualitative input and new guideline questions submitted to IRB
IRB approval
Revised guidelines submitted to Delphi Panel (Round 2)
14 of 14 responses
Guidelines not reaching consensus revised based on qualitative input and new guideline questions submitted to IRB
IRB approval
Revised guidelines submitted to Delphi Panel (Round 3)
14 of 14 responses
Final analysis:
7 of 8 initial guidelines reached consensus

Appendix 1. Exclusion Criteria: ICD-9, ICD-10, and HCPCS Codes for Exclusions

Exclusions summary (see Appendix 1 tables below for additional details):

- Patients with a contraindication to NSAIDs
- Patients undergoing caesarean delivery
- Patients with selected complicated deliveries
- Patients undergoing tubal ligation during the index hospitalization
- Death during the index hospitalization
- Patients from hospitals with volumes below 36 deliveries within the three-year study window
- Patients from hospitals that do not have at least one delivery in each of the three calendar years (2014-2016)

ICD-9 DM Code	Code Description	Exclusion Category Grouping
580 – 587	Renal disease	NSAID contraindication
287.3X – 287.4X	Thrombocytopenia	NSAID contraindication
286	Coagulation disorders	NSAID contraindication
649.3X	Coagulation defects complicating pregnancy, childbirth, or the puerperium	NSAID contraindication
642.1X	Hypertension secondary to renal disease complicating pregnancy childbirth and the puerperium	NSAID contraindication
646.2X	Unspecified renal disease in pregnancy without mention of hypertension	NSAID contraindication
649.8X	Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks' gestation, with	Caesarean delivery

	delivery by (planned) cesarean section	
669.7	Cesarean delivery without mention of indication	Caesarean delivery
651 – 659	Care in Pregnancy, Labor, And Delivery	Complicated delivery
630 – 639	Ectopic and Molar Pregnancy and Other Pregnancy with Abortive Outcome	Complicated delivery
660 – 669	Complications Occurring Mainly in the course of Labor and Delivery	Complicated delivery
66.2X – 66.3X	Bilateral Endoscopic Destruction or Occlusion of Fallopian Tubes	Tubal ligation

ICD-9 Procedure Code	**Code Description**	**Exclusion Category Grouping**
74	Cesarean Section and Removal of Fetus	Caesarean delivery
72	Forceps, Vacuum, And Breech Delivery	Complicated delivery
73.0X-73.4X, 73.51, 73.6X-73.9X	Other Procedures Inducing or Assisting Delivery	Complicated delivery
75.0X-75.33, 75.35-75.99	Other Obstetric Operations	Complicated delivery

ICD-10 Code	**Code Description**	**Exclusion Category Grouping**

N00 – N19	Renal disease	NSAID contraindication
D69.3 – D69.6	Thrombocytopenia	NSAID contraindication
D65 – D68	Coagulation disorders	NSAID contraindication
O26.83	Pregnancy related renal disease	NSAID contraindication
O99.1	Other diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism complicating pregnancy, childbirth and the puerperium	NSAID contraindication
O82	Encounter for cesarean delivery without indication	Caesarean delivery
O00 – O08	Pregnancy with abortive outcome	Complicated delivery
O61 – O71	Complications of labor and delivery	Complicated delivery
O75.4 – O75.8	Complications of labor and delivery	Complicated delivery
0W8NXZZ	Division of Female Perineum, External Approach	Complicated delivery

0UL7	Fallopian Tubes, Bilateral	Tubal ligation
102	Obstetrics, Pregnancy, Change	Complicated delivery
109	Obstetrics, Pregnancy, Drainage	Complicated delivery
10A	Obstetrics, Pregnancy, Abortion	Complicated delivery
10D	Obstetrics, Pregnancy, Extraction	Caesarean delivery
10H	Obstetrics, Pregnancy, Insertion	Complicated delivery
10J	Obstetrics, Pregnancy, Inspection	Complicated delivery
10P	Obstetrics, Pregnancy, Removal	Complicated delivery
10Q	Obstetrics, Pregnancy, Repair	Complicated delivery
10S	Obstetrics, Pregnancy, Reposition	Complicated delivery
10T	Obstetrics, Pregnancy, Resection	Complicated delivery
10Y	Obstetrics, Pregnancy, Transplantation	Complicated delivery

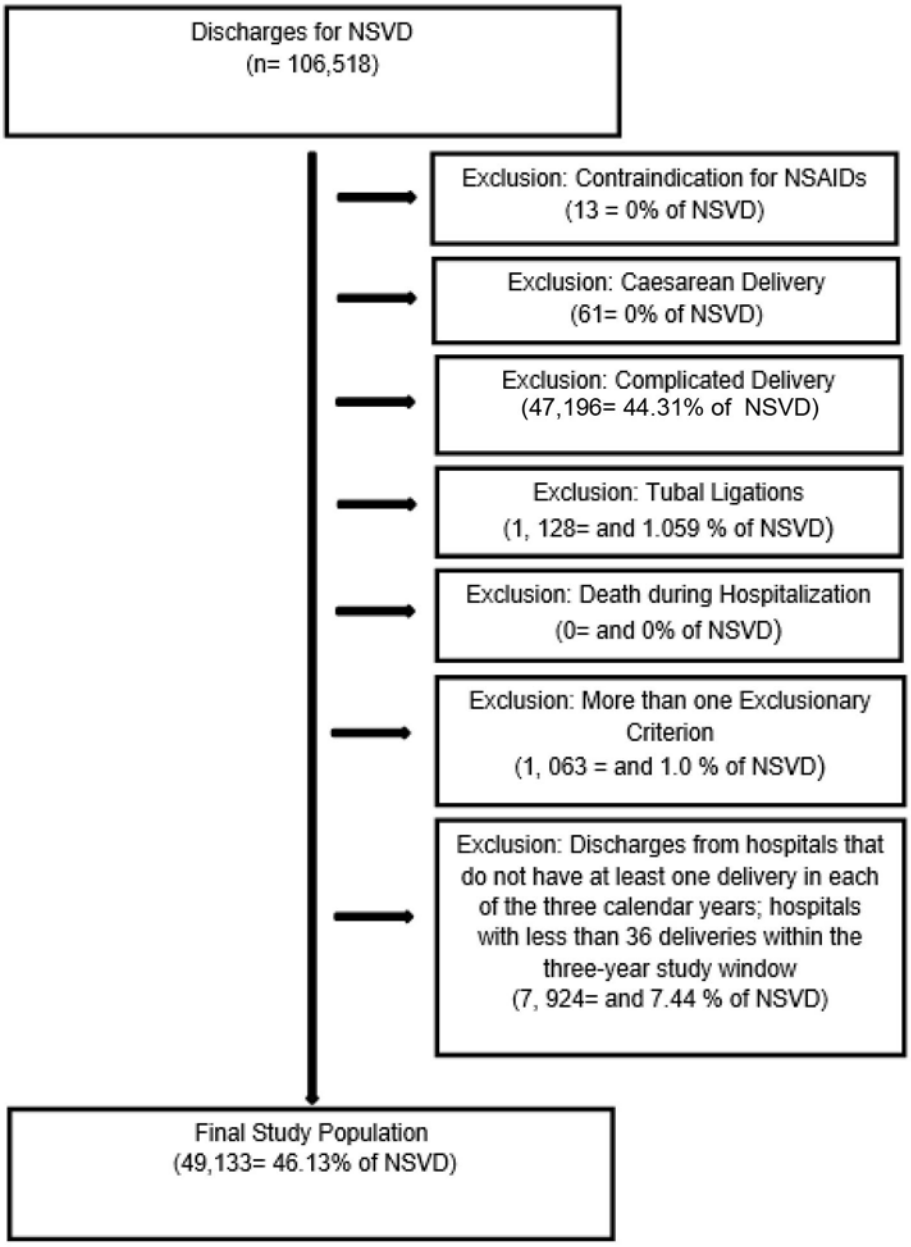
HCPC Code	**Code Description**	**Grouping**
1961	Anesthesia for Cesarean Delivery	Caesarean delivery
1963	Anesthesia for Cesarean Hysterectomy without any Labor Analgesia/Anesthesia Care	Caesarean delivery

1968	Anesthesia for Cesarean Delivery Following Neuraxial Labor Analgesia/Anesthesia	Caesarean delivery
1969	Anesthesia for Cesarean Hysterectomy Following Neuraxial Labor Analgesia/Anesthesia	Caesarean delivery
59510	Routine Obstetric Care Including Antepartum Care, Cesarean Delivery and Postpartum Care	Caesarean delivery
59514	Cesarean Delivery Only	Caesarean delivery
59515	Cesarean Delivery Only; Including Postpartum Care	Caesarean delivery
59618	Routine Obstetric Care Including Antepartum Care, Cesarean Delivery, and Postpartum Care, Following Attempted Vaginal Delivery After Previous Cesarean Delivery	Caesarean delivery
59620	Cesarean Delivery Only, Following Attempted Vaginal Delivery After Previous Cesarean Delivery	Caesarean delivery
59622	Cesarean Delivery Only, Following Attempted Vaginal Delivery After Previous Cesarean Delivery; Including Postpartum Care	Caesarean delivery

59300	Episiotomy or Vaginal Repair, by other than Attending	Complicated delivery
58600 - 58615	Tubal Ligation	Tubal ligation

Key: ICD: International Classification of Diseases; HCPC: Healthcare Common Procedure Coding System

Appendix 2. Study population identification. NSVD, normal spontaneous vaginal delivery; NSAIDs, nonsteroidal anti-inflammatory drugs.



Appendix 3. Patient and Hospital Variables for Each Patient Discharge for Opioid Administration During Hospitalization and on Day of Discharge

Patient Variables for Each Discharge Included in Bivariate Analysis	
Age	15-18
	19-34
	35-44
Marital Status	Married
	Single
	Other/Unknown
Race	White
	Black
	Other/Unknown
Ethnicity	Hispanic or Latino
	Unknown
Payor Type	Medicaid
	Commercial
	Managed Care
	Other
Drug Dependence (as defined by ICD-9 Diagnoses Codes 648.3 or ICD-10 Diagnoses Codes O99.32x or F11 (F11.1-F11.99)	Yes
	No
Benzodiazepine used on Same Day as Opioid	Benzodiazepine used on Same Day
	No use of benzodiazepines
Year of Discharge	2014
	2015
	2016

Route of Administration of Opioid (determined separately for both during hospitalization and on day of discharge)	Non-PO (Iv, IM, Topical – one or any combination of the three routes)
	PO and non- PO
	PO only
Hospital Variables for Each Discharge Included in Bivariate Analysis	
LOS	Mean-Std Dev
	Median
	IQR
	Min/Max
Bed Size	<100
	100-199
	200-299
	300-499
	500+
Nine Census Regions	New England
	Mid-Atlantic
	South Atlantic
	NE Central
	SE Central
	NW Central
	SW Central
	Mountain
	Pacific
Teaching Status	Teaching
	Non-teaching
Urbanicity	Rural
	Urban

0 **Appendix 4. Panel Participants and Credentials (in Alphabetical Order)**

Name	**Leadership Role and Affiliation(s)**
Tamika Auguste, MD	Associate Medical Director, Medstar Health Simulation Training & Education Lab Associate Professor, Obstetrics and Gynecology, Georgetown School of Medicine
Peter Bernstein, MD, MPH	Director, Division of Maternal Fetal Medicine Professor of Obstetrics & Gynecology and Women's Health Albert Einstein College of Medicine/Montefiore Medical Center
Ann E.B. Borders, MD, MSc, MPH	Maternal-Fetal Medicine, Evanston Hospital, NorthShore University HealthSystem Clinical Associate Professor, University of Chicago, Pritzker School of Medicine Adjunct Assistant Professor Department of Medical Social Sciences, Center for Healthcare Studies, Institute for Policy Research, Northwestern University Executive Director, Illinois Perinatal Quality Collaborative
Siobhan Dolan, MD	Professor and Vice Chair, Research, Department of Obstetrics and Gynecology and Women's Health, Montefiore Health System

Timothy J. Fisher, MD, MS	Obstetrics and Gynecology Residency Program Director Interim Director, Division of General Obstetrics and Gynecology Assistant Professor, Obstetrics and Gynecology Dartmouth-Hitchcock Medical Center and The Geisel School of Medicine at Dartmouth Medical Director, Northern New England Perinatal Quality Improvement Network
Alex Friedman, MD	Assistant Professor, Obstetrics & Gynecology, Columbia University College of Physicians and Surgeons
William Grobman, MD	Arthur Hale Curtis Professor Vice Chair, Department of Obstetrics and Gynecology Medical Director, NMG Women's Health Feinberg School of Medicine at Northwestern University
Victor R. Klein, MD, MBA, CPHRM, FACOG, FACMG, FASHRM	Vice Chairman, Quality and Patient Safety, Obstetrics and Gynecology Service Line, Northwell Health Associate Professor of Obstetrics & Gynecology, Zucker School of Medicine at Hofstra/Northwell Perinatalogist, Department of Obstetrics and Gynecology, North Shore University Hospital.
David Lagrew, MD	Executive Medical Director of Women's Service, St. Joseph-Hoag Health Region of Providence Healthcare

Elliott Main, MD	Medical Director, California Maternal Quality Care Collaborative
Christian Pettker, MD	Associate Professor of Obstetrics, Gynecology, and Reproductive Sciences Chief of Obstetrics, Yale School of Medicine and Yale-New Haven Hospital Medical Director, Labor & Birth Unit and Maternal Special Care Unit, Yale-New Haven Hospital
Mona Prasad, DO, MPH	Assistant Professor, Department of OB/GYN, Division of Maternal Fetal Medicine, The Ohio State University Medical Center
Mishka Terplan, MD, FACOG	Associate Medical Director, MedStar Health Simulation Training & Education Lab (SiTEL) Associate Professor, Obstetrics and Gynecology, Georgetown School of Medicine
Tricia Wright, MD, MS, FACOG, FASAM	Associate Professor Department of Obstetrics, Gynecology and Women's Health Clinical Associate Professor, Department of Psychiatry University of Hawaii John A. Burns School of Medicine

Appendix 5. Opioid Administration by Route During Hospitalization in U.S. NSVD Patients January 1, 2014-December 31, 2016

Population	Overall (%)	2014 (%)	2015 (%)	2016 (%)
NSVD, n	49,133	17,357	17,188	14,588
NSVD, without any opioid, n (%)	10,701 (21.8%)	3,782 (21.8%)	3,656 (21.3%)	3,263 (22.4%)
NSVD with any opioid during hospitalization, n (%)	38, 432 (78.2%)	13,575 (78.2%)	13,532 (78.7%)	11,325 (77.6%)
NSVD with only non-PO opioid during hospitalization, n (%)	14,673 (29.9%)	4,957 (28.6%)	5,078 (29.5%)	4,638 (31.8%)
NSVD with only PO opioid during hospitalization, n (%)	7,760 (15.8%)	2,841 (16.4%)	2,775 (16.1%)	2,144 (14.7%)
NSVD with both PO and non-PO opioid during hospitalization, n (%)	15,999 (32.6%)	5,777 (33.3%)	5,679 (33.0%)	4,543 (31.1%)

Key: NSVD: normal spontaneous vaginal delivery; PO: *per os*/oral

Mills JR, Huizinga M, Robinson S, Lamprecht L, Handler A, Petros M, et al. Draft opioid prescribing guidelines for uncomplicated normal spontaneous vaginal birth. Obstet Gynecol 2019; 133.
The authors provided this information as a supplement to their article.