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Maternal Quality and Safety Indicators Databook 2001-2006

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Human Subjects Protocol

FHOP's research protocol is entitled "Longitudinal Study of Hospital Outcomes for California's Children." The protocol has been amended from time to time to add more years of data and datasets. In terms of age, the protocol now includes infants, children, youth, and the population of reproductive age. This work requires two protocols. The protocol through the Committee on Human Research, University of California San Francisco, is Number H6433-12769-13. The Protocol through the Committee for the Protection of Human Subjects, State of California, Health and Human Services Agency is Number 96-06-02.

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MATERNAL QUALITY AND SAFETY INDICATORS
2001-2006 DATABOOK

In response to rising maternal mortality rates, the California Department of Public Health Maternal Child and Adolescent Health (MCAH) Branch instituted the Maternal Care Quality Improvement Project to address maternal morbidity and mortality. Under auspices of the Bay Area Data Collaborative (BADC), ten MCAH jurisdictions in the San Francisco Bay Area applied as a group to do a regional analysis and plan. These jurisdictions are Alameda, Contra Costa, Marin, Napa, Santa Clara, San Francisco, San Mateo, Solano, and Sonoma counties, and the City of Berkeley. They entered into this joint project as an opportunity to do a more meaningful analysis and to develop a more comprehensive plan than they could do independently. In this context, the Family Health Outcomes Project at the University of California, San Francisco was asked to:

- Identify regional variations in maternal morbidity and mortality that are associated with poor outcomes, have a large population impact, and are amenable to intervention.

- Prepare health jurisdiction databooks highlighting important conditions to monitor

As a result of the activities FHOP undertook for the BADC, we identified that cesarean delivery and patient safety indicators (PSI) are important conditions to monitor.[1] This document introduces the maternal quality and safety indicators databook and discusses implications for using it to inform local monitoring and planning activities.

INDICATORS

Unlike other health indicators, the quality of inpatient care and patient safety are largely controlled by the hospital. Thus, while other databooks are based on county of residence, maternal quality indicators are based on the county where women deliver their babies.

The Agency for Healthcare Research and Quality (AHRQ) developed an extensive group of software products to evaluate the quality and safety of care provided in hospitals and regionally by place of occurrence.[2] [3] In developing this databook, we relied extensively on AHRQ's publicly available software.

CESAREAN DELIVERIES

Cesarean delivery rates are considered utilization indicators. The use of cesarean procedures varies significantly across hospitals and questions have been raised about their overuse, underuse, or misuse.[2] Cesarean rates become inpatient quality indicators when high-risk cases are excluded and rates are adjusted as they are for the AHRQ Inpatient Quality Indicators (IQI).

Lowering the cesarean rate has been a national goal for more than two decades.[4] Although the appropriate target for the rate as well as best methods to safely lower it have been debated, the federal government set a goal in the 1990s to achieve no more than 15 cesarean deliveries per 100 births by the year 2000. When objectives were evaluated for Healthy People 2010, the focus of the objective changed from all women giving birth to low-risk women - those having singleton babies at 37 weeks gestation or more. Coming into the new century, Figure 1 shows that California's total cesarean rate was in the nation's highest quintile in 1999.

Figure 1. Total cesarean rates by State: United States 1999

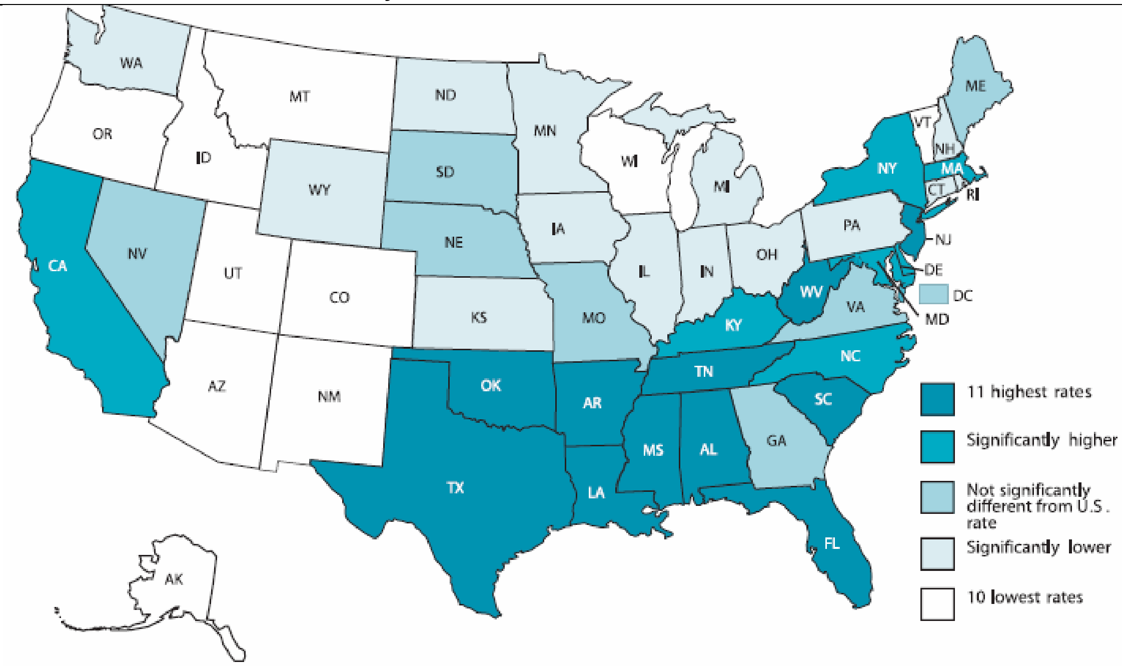


Figure 2. Total primary and cesarean rates and vaginal birth after previous cesarean rate: United States, 1991-2000.

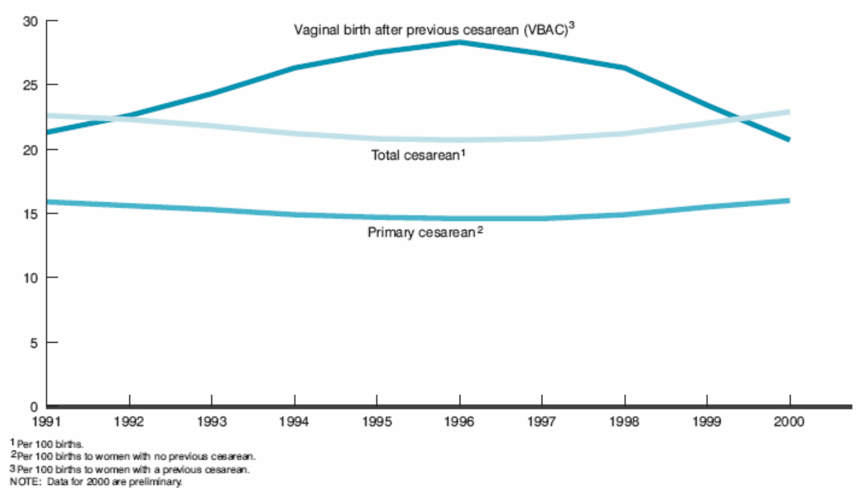


Figure 2 shows that cesarean rates dropped through the mid-1990s and rose thereafter. By 2006, the national cesarean rate was 30%.[5]

Because vaginal birth after a previous cesarean (VBAC) have become uncommon, we do not include this delivery mode as a quality indicator. VBACs declined steadily since the mid 1990s after studies found significant maternal morbidity and mortality attached to this delivery mode.[6 7 8] In 1999 only 97,680 births nationally were delivered by VBAC.[9] Between 2001 and 2006 the percent of California VBAC deliveries dropped from 2.8% to 1.2%.

The following figures compare California and US trends for total cesarean deliveries and non-routine discharges, and within California, trends for non-routine discharges, extended length of stay (ELOS), and patient safety measures. AHRQ recommends that cesarean and patient safety indicators be evaluated relative to these other measures. When cesarean trends rise, ELOS tends to rise and PSI tend to go down, because maternal PSI focus primarily on vaginal deliveries. Hospitals are understandably reluctant to code PSI. Thus ELOS and non-routine discharges can be used as secondary measures to try to understand what is happening. If hospitals have a low cesarean rate, a low PSI rate, but high rates of ELOS or non-routine discharges, the PSI rate may be under-reported.

Figure 3. Total cesarean rate trends California and US 2001-2006

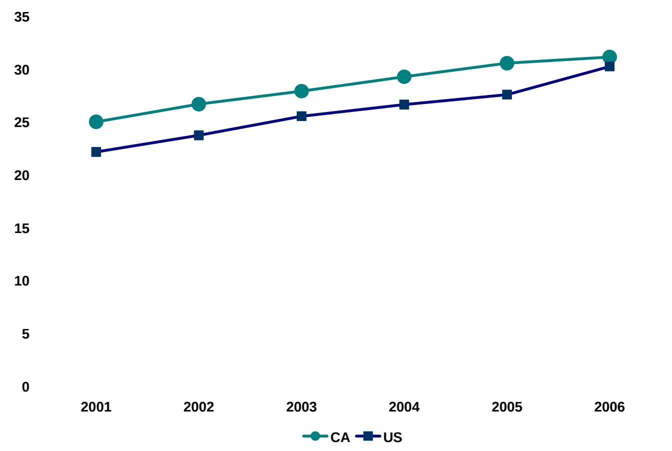


Figure 3 compares California's total cesarean rate to the rate reported by the National Center for Health Statistics. Although California's cesarean rate has been high, the national trend has been climbing 1.55% per year, while California's has been climbing 1.24%. By the end of the trend period, California's total cesarean rate was not different from the nation's although both rose significantly.

Figure 4. Non-routine discharge trends California and US 2001-2006

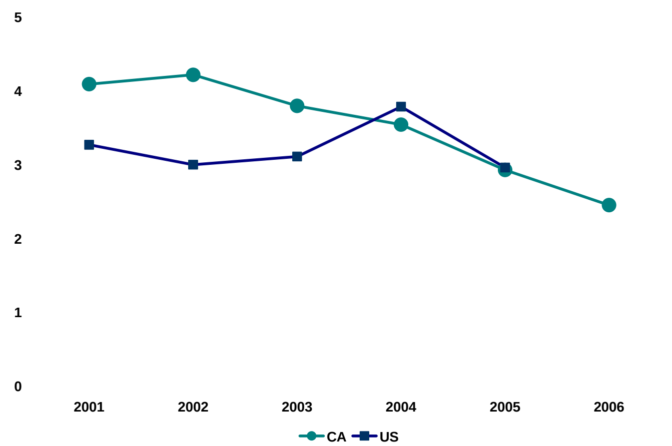


Figure 4 compares non-routine maternity discharge trends for California and the US. A non-routine discharge is any disposition but return home. California was higher than the nation through 2004. National data for 2006 have not yet been released.

Figure 5. Trends for other care quality indicators

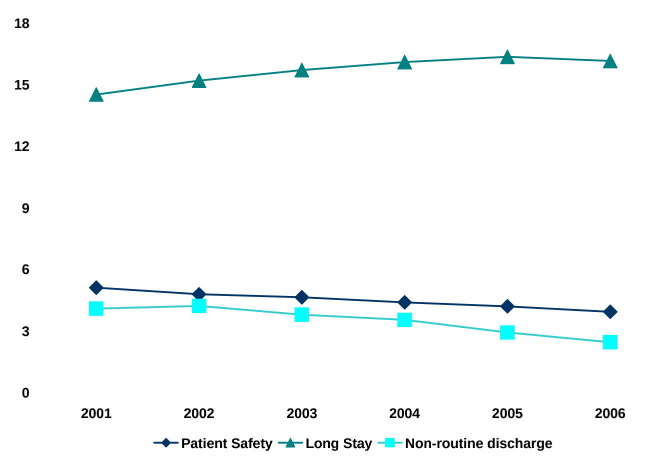


Figure 5 compares California trends for patient safety indicators (PSI), ELOS (stays 4+ days long), and non-routine discharges. LOS for MDC 14 (pregnancy and puerperium) has been rising in California and the US, because the cesarean rate is rising. California's average LOS was not importantly different from the nation's over the study period. Increasing cesarean rates affect PSI and non-routine discharge rates.

The maternal quality databook focuses on three measures of cesarean delivery that can be calculated from hospital data.

- **Total Cesarean Rate** can be directly compared with national statistics released by the National Center for Health Statistics (NCHS). The number of deliveries by cesearean section is divided by total number of deliveries, and the product is multiplied by 100.[5] Cesarean section procedures were defined using AHRQ's Clinical Classification Software.[10] Delivery DRGs are in the range 370-375.

- C**esarean Rate (IQI 21)** is a measure AHRQ developed for its inpatient quality (IQI) software. Inclusion and exclusion criteria are specified in a publication available from AHRQ.[11] To calculate IQI 21, the AHRQ software removes high-risk deliveries from the delivery cohort, looks within the remainder of cases to find cesarean deliveries, and adjusts the rate by age. The final rate is not comparable to published NCHS rates which exclude "high risk" cases, but are not otherwise adjusted.[5]

- **Primary Cesarean Rate (IQI 33)** is another AHRQ inpatient quality measure that cannot be compared directly with NCHS statistics.[5] IQI 33 inclusion and exclusion criteria are specified in a publication available from AHRQ.[11] The AHRQ software removes women with high-risk deliveries and women who previously had a cesarean section from the cohort of women delivering infants, identifies women within the remainder of cases to find women having their first cesarean, and adjusts the rate by age.

PATIENT SAFETY

Patient Safety Indicators (PSI) are a set of measures AHRQ developed to screen for adverse events patients experience as a result of exposure to the health care system. The PSI relate to inpatient care and are not measured in outpatient settings. PSI rates vary substantially and significantly across hospitals, and have acceptable validity and reliability.[12] These events are likely amenable to prevention by changes at the system or provider level.[3]

PSIs do not capture "near misses" or undocumented adverse events. For example, AHRQ has yet to develop a PSI for postpartum hemorrhage. They also do not include adverse events related to a number of important patient safety concerns that are not reliably specified using ICD-9-CM. Examples might include giving insulin to a woman who is not diabetic or a woman falling while trying to get to the toilet after delivery.

Some other adverse outcomes such as puerpueral fever are preventable but often do not manifest until after discharge.[13] [14] [15] [16] In one followup study, adverse outcomes manifested in about 25% of patients after discharge; most adverse events caused symptoms but did not result in an emergency department visit, hospitalization, or death.[15] Another study found prevalence of medical errors following hospitalization was high because of discontinuity between the inpatient and outpatient setting, which resulted in an increased rate of rehospitalization.[15]

Because of variation in definitional criteria, a patient can be included in or excluded from more than one PSI. Patients who are mentally ill, substance abusers, or pregnant are specifically excluded from many PSI. The only PSI indicator specific to obstetrics is third and fourth degree perineal trauma. Finally, rates are based on different denominators (per 100, 1,000, etc) because many PSI are rare. Table 1 summarizes variations in numbers of eligible cases, events, rate multipliers, and observed rates for PSI that could be calculated for cases included in the study of California maternal morbidity and mortality.[1]

Table 1. Patient Safety Indicator

Patient Safety Indicator		Eligible	Cases	Rate Per	Rate
PSI 01	Anesthesia complications	993,759	403	10,000	4.1
PSI 02	Death low mortality DRG	3,138,609	241	100,000	7.7
PSI 05	Foreign body left during procedure	3,144,478	114	100,000	3.6
PSI 07	Infection due to medical care	2,548,889	137	100,000	5.4
PSI 18	OB trauma-vaginal w instrument	239,591	37,413	100	15.6
PSI 19	OB trauma-vaginal w/o instrument	2,006,952	76,553	100	3.8
PSI 20	OB trauma-C-section	897,935	2,885	1,000	3.2
Any	Any Patient Safety Indicator	3,144,478	117,733	100	3.7
Defined	Defined Adverse Event	3,144,478	22,024	1,000	7.0
Either	Any PSI or Defined Adverse Event	3,144,478	138,278	100	4.4

In 2003, the national rate for OB trauma-vaginal with instrument was about 23/100, and for vaginal without instrument, about 9/100.[17] While most adverse events are uncommon, they vary importantly by delivery method, and are highly related to maternal mortality. The following table is from the final report analyzing data for all pregnant women admitted to California hospitals between 2001 and 2006.[1]

Table 2. Summary of findings regarding PSI at discharge and person levels

Discharge Level	Patient Safety	4% had a PSI 60% of in-hospital deaths had a PSI 90% of delivery deaths had a PSI
	Of deliveries or other pregnancy terminations that the woman survived	1.0% of terminations had a PSI 1.9% of cesarean deliveries had a PSI 5.2% of vaginal deliveries had a PSI 6.6% of VBACs had a PSI
Person Level	Patient Safety	5.6% had a PSI 37% of deaths had a PSI

For the databook, we created a single summary variable flagging the occurrence of any PSI or any discharge with a defined adverse ICD-9 code. The databooks report an adjusted rate, calculated using modified PSI software. The adjustment method is described in Appendix A. Overall, adverse events declined over the period, and PSI trends are consistent with trends in "harder" outcomes such as cesarean delivery, ELOS, and non-routine discharges.

THE IMPORTANCE OF PLACE

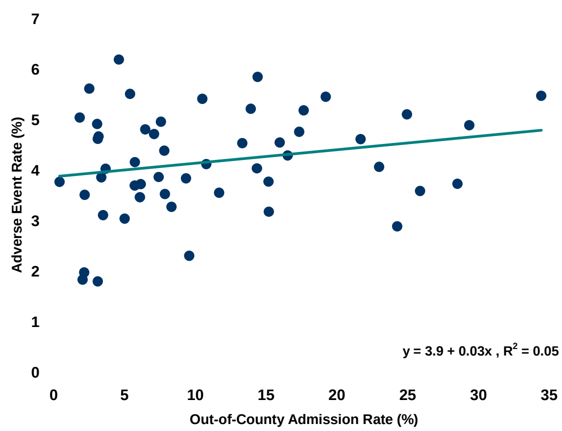
The underlying rationale that led to forming the BADC was recognition by local health jurisdictions that maternal health was best approached as a regional issue in the Bay Area. These jurisdictions recognized that, because of the way healthcare is organized in this region, they were caring for each other's residents and they would have to think and act regionally to address the quality of maternal outcomes.

In 2001, 9.2% of pregnant California women were admitted to out-of-county (OOC) hospitals. By 2006, the rate rose to 10%. Over the 6-year period, the average OOC rate was 9.6% with a range from a low of 0.8% (San Diego) to 100% (several rural counties with no hospitals). Only about 1 in 3 counties had an OOC rate lower than the State based on place of residence.

Several small counties have done well in maintaining local access to hospitals, while many urban counties have OOC rates near the top of the state range. As a region, the Bay Area OOC rate based on residence was twice as high as the state rate, and only 2 of the 9 counties had rates below the state average.

When maternal data were evaluated based on place of occurrence, that is, where deliveries occurred, hospitals in about half of the counties admitted more than 10% of cases from outside their county of licensure. The range was from a high of 65% to a low of 0.2%. Again, differences were against expectations with respect to county size or urban/rural. Only one Bay Area county admitted a percent of OOC patients below the state rate based on place of occurrence.

Figure 6. Relationship between the out-of-county admission and patient safety rates based on county of delivery



We compared the relationship between the patient safety and OOC rates based on county of occurrence (where the mother delivered), weighted by the number of admissions. As the regression line in Figure 6 shows, each 1% increase in a county's OOC admissions was predicted to increase the PSI rate by 0.3%.

While we do not fully understand the relationship between OOC care and adverse events, we have found it in other studies. It is associated with underlying changes in hospital infrastructure that may be good for hospital systems but appear not to be good for patient outcomes.[18 19 20]

Confirming AHRQ's underlying premise, maternal outcomes are related to place. Local practice patterns strongly influence both delivery mode (vaginal, cesarean, VBAC) and adverse events.

On average, in California, the greater the rate at which a county's residents go OOC to deliver, the higher the proportion of adverse events that can be anticipated, all things being equal. Counties with a large proportion of residents delivering OOC will need to know the counties and hospitals admitting their residents. We do not know if similar relationships hold in other states.

LAYOUT

The maternal quality databook contains four types of tabs: Data, Place, Rates, and Graphs.

Data Tabs. The Data Tabs are a 2-tab set with 6 years of maternal outcomes data by place of occurrence. Each Data Tab presents the numerators with the appropriate denominators to calculate raw rates. The first tab contains data for the local health jurisdiction. The second contains data for the state.

Place Tab. The Place Tab summarizes all six years of maternal quality data in two ways: the county where delivery occurred and the county where the mother resided.

The Rate Tab is preset to print in three pages.

Page 1 defines the indicator and its risk factors. Below this is the rate table. The Total Cesarean rate and confidence interval is unadjusted. Rates and confidence for other indicators were adjusted using AHRQ software. The rate table may have 6 data rows or may have none, depending on the number of cases available over the trend period. Rules for determining the number of rows are in the next section of this document. Below the rate table on page 1, we identify the data sources and additional analyses you might wish to undertake to understand your jurisdiction's performance on the indicator.

Page 2 of the rate tab summarizes rates for White Non-Hispanic and Hispanic All-Race, and Page 3 summarizes results for Non-Hispanic African-American and Asian populations. We used the same rules to calculate these tables as we used for the Total table.

The Graph Tab . This summarizes results of trend tests for adjusted data on the Rate Tab. As with the Rate Tab, page 1 summarizes results for all data, page 2 for White Non-Hispanic and Hispanic All-Race, and page 3 for Non-Hispanic African American and Asians. Methods for calculating trend statistics are described in Appendix B.

CALCULATING ANNUAL ADJUSTED RATES

MINIMUM NUMBER OF EVENTS

If the minimum number of events over all years was greater than or equal to 10 in each year, the 6 years of indicator data was left as given.[21] In this databook, we have only 6 years of data to trend and thus do not further group years. If we did not have have the minimum cases over all six years, the Rates tab will have the phrase "Rates not calculated." Otherwise, the Rates Tab tables show the periods, numerators, rates, and confidence intervals.

Given the final level of aggregation for the local data, the same aggregation was performed on the corresponding California data. Then the local and state data were merged for side-by-side presentation in the Rate Tab.

DENOMINATORS

In this databook, each indicator has different denominators based on inclusion and exclusion criteria. The denominator is defined in the rate tab for each indicator. Denominator counts are found on the Local or State tabs.

CALCULATING RATES AND CONFIDENCE INTERVALS

This databook departs from others in the FHOP series in that it presents raw rates for total cesarean deliveries and adjusted rates for the other indicators. Race/ethnicity and geographic variables were calculated as described elsewhere.[25]

- **Total cesarean rate**. This was calculated for each race/ethnic group and geographic level by dividing the numerator (number of events) by the total number of records in DRGs 370 through 375. Cases were identified for the numerator by searching over the array of procedures to identify any cesarean procedure as defined by CCS software. The result was multiplied times 100 to get a percent. The rate confidence interval was calculated using the Wilson score without continuity correction.[26] [27] This is the standard method followed in all other databook products.

- **Cesarean** and **primary cesarean rates**. Cases were identified using AHRQ software. Individual risk for these delivery modes was estimated using national IQI age parameter estimates provided with the AHRQ software. Then the data were stratified and summarized by race/ethnicity and geographic level. The rate table shows the adjusted rate and adjusted confidence intervals. The adjusted rate and confidence intervals were calculated as described below. Raw rates and confidence intervals could be calculated from information on the Data Tabs using the appropriate FHOP rate template.

- **Patient safety rate.** This rate was calculated in a two-step fashion.We used AHRQ software to select cases eligible for defined PSI events in Table 1 and to find cases where the event occurred.[28] We identified cases with defined adverse events using FHOP software based on the CCS.

  Next, we estimated individual risk for each indicator. If national parameter estimates for comorbid conditions were available from AHRQ for a given PSI, we used those to estimate probability. Some safety indicators have no comorbidity estimates, for example mortality in a low-risk DRG. Defined adverse events also have no estimated probability because risk is provider-based. An example would be administering medicine (insulin) to a patient who does not have the condition (diabetes). For these, we used as an estimate the statewide rate at which the event occurred. Thus, from Table 1, the estimated probability for death in a low mortality DRG (PSI 02), was 241/3,138,069, or 0.0007648.

  After estimating risk for each adverse event, we set up the array of safety indicators and selected the maximum risk found over all indicators as the predicted risk for the summary safety variable. After selecting the best predicted probability, we stratified and summarized the data by race/ethnicity and geographic level using a combination of FHOP and AHRQ methods described below to calculate adjusted rates and adjusted confidence intervals.[28]

  The Patient Safety rate table displays adjusted rates and confidence intervals. Raw rates and confidence intervals can be calculated from information on the Data Tabs using the appropriate FHOP template.

- **Rate adjustment method**. The adjusted rate and confidence interval were calculated as follows. First, a regular rate and confidence interval were calculated using the Wilson score without continuity correction. As was done in the AHRQ software, the rate and confidence interval were multiplied by an adjustment factor to yield the adjusted rate and adjusted confidence interval. The adjustment factor was the state-wide average risk for the indicator divided by the average risk for the patients used in calculating the rate. See Appendix A for more details.

EXAMPLE PLACE TAB

The Place Tab summarizes the maternal indicator data by county of occurrence and county of residence over the entire period 2001 to 2006. In Table 3, we focus on the place of occurrence section. This table summarizes the observed cesarean and outcomes rates for the county where deliveries occurred. For simplicity, this table does not include confidence intervals. Adjusted county-level rates and adjusted confidence intervals are available in each county's databook, for adjusted cesarean deliveries and the adjusted patient safety measure. This sheet gives all counties a general sense of how hospitals in their jurisdiction perform.

Table 3. Example Place Tab

	Place of Occurrence - % Observed							
			Cesarean			Outcomes		
Jurisdiction	**Patients**	**Out-of-County**	**Total**	**IQI 21**	**IQI 33**	**Safety**	**Long Stay**	**Non-Routine**
0 State	3,475,593	9.6	25.7	20.2	12.7	4.2	14.4	3.2
1 Alameda	141,462	17.2	23.2	18.1	11.9	4.8	16.3	11.0
2 Alpine								
3 Amador	1,280	25.7	28.6	21.4	12.3	3.6	11.6	1.6
4 Butte	18,440	21.5	22.9	18.5	10.1	4.6	8.0	4.4
5 Calaveras	900	24.8	22.9	18.9	9.0	5.1	8.7	14.2
6 Colusa	1,366	10.3	24.2	21.2	14.9	5.4	12.2	58.1
7 Contra Costa	76,982	19.0	23.0	17.6	10.8	5.5	15.9	7.6
8 Del Norte	1,696	0.2	19.9	16.3	7.7	3.8	6.4	1.3
9 El Dorado	6,461	6.9	24.3	19.6	11.4	4.7	7.0	1.3
10 Fresno	108,813	11.5	26.3	20.7	11.8	3.6	9.1	1.1

Stays longer than 4 days and non-routine discharges are included in this table because AHRQ recommends examining these to understand variation in practice patterns when evaluating quality indicators.[31] Cesarean rates, long stays and non-routine discharges are "harder" measures than patient safety indicators. Hospitals are uncomfortable identifying adverse outcomes in their patient population. When things go wrong, some hospitals transfer patients to another hospital, while others continue to treat the patient until she recovers.

EXAMPLE RATE TAB

Table 4 is an example of the Rate Tab for one indicator, in this case the primary cesarean rate (IQI 33). The top section includes definitions of the indicator, numerator, denominator, the Healthy People 2010 Objective, and exclusion criteria associated with this indicator.

Table 4. Primary cesarean deliveries (IQI33) by Race/Ethnicity

DEFINITION: **IQI 33 -** The number of primary cesarean deliveries per 100 eligible deliveries by place of occurrence

NUMERATOR: Number of cesarean deliveries, identified by DRG, or by ICD-9-CM procedure codes if they are reported without a 7491 hysterotomy procedure, among cases meeting the inclusion and exclusion rules for the denominator.

DENOMINATOR: Total number of deliveries with no previous cesarean in DRG 370 to 375 after exclusions

HP 2010 OBJECTIVE: 16.9 Reduce cesarean births among low-risk women to 15% of live births

EXCLUSION: Abnormal presentation, preterm delivery, fetal death, multiple gestation diagnosis codes, breech procedure codes, previous Cesarean delivery diagnosis in any diagnosis field

TOTAL POPULATION								
	California				Local			
		Adjusted	Confidence Limit			Adjusted	Confidence Limit	
Year	Deliveries	Rate	Lower	Upper	Deliveries	Rate	Lower	Upper
2001	61,386	15.0	14.9	15.1	10,507	13.4	13.1	13.6
2002	66,368	16.2	16.1	16.3	11,409	14.5	14.3	14.8
2003	71,450	17.1	17.0	17.2	11,655	14.8	14.6	15.1
2004	76,436	18.3	18.2	18.4	11,873	15.3	15.1	15.6
2005	81,525	19.4	19.3	19.5	12,504	16.3	16.1	16.6
2006	85,494	19.9	19.7	20.0	12,773	16.5	16.2	16.8

Sources: **Objective:** http://www.healthypeople.gov/document/html/objectives/16-09.htm

Definition: Guide to Inpatient Quality Indicators: Quality of Care in Hospitals – Volume, Mortality, and Utilization. Department of Health and Human Services Agency for Healthcare Research and Quality http://www.qualityindicators.ahrq.gov June 2002 Version 3.1 (March 12, 2007) **IQI 33**

Numerator: Primary cesarean deliveries as defined by AHRQ for use in standard inpatient hospital datasets such as those distributed by the California Office of Statewide Health Planning and Development. In this instance, the numerator is the number of Cesarean deliveries, identified by DRG, or by ICD-9-CM procedure codes if they are reported without a 7491 hysterotomy procedure, among cases meeting the inclusion and exclusion rules for the denominator.

Denominator: All deliveries as defined by AHRQ for use in standard inpatient hospital datasets such as those distributed by the California Office of Statewide Health Planning and Development. Specifically, all deliveries except cases: with abnormal presentation, preterm, fetal death, multiple gestation diagnosis codes, breech procedure codes, or previous Cesarean delivery diagnosis in any diagnosis field.

Recommended Tables: ***Can be analyzed using EpiBC***

Cesarean deliveries by mother's race/ethnicity
Delivery mode by mother's age
Delivery mode by payor
Cesarean deliveries by place of occurrence

Notes: Cesarean delivery has been identified as an overused procedure. As such, lower rates represent better quality. However, the upper and lower bounds of what constitutes "acceptable" cesarean rates has not been empirically determined. Cesarean delivery rates were calculated using software develped by AHRQ for use in hospital discharge data. The AHRQ uses cesarean rates as a marker of inpatient quality. The AHRQ software excludes high-risk cases. Cesarean rates are highly sensitive to provider practice patterns. For this reason, we focus this indicator on place of occurrence rather than place of residence.

C.L. = Confidence Limit = the boundary of the 95% confidence interval.

The Rate Table shows data for the total population in California and the local jurisdiction, over the most recent 6-year period for which data are available, in this case 2001 through 2006. For both California and the jurisdiction, columns indicate the number of events, the adjusted rate, and adjusted lower and upper confidence limits for that rate.

Below the rate table, we present information on the sources for the definitions of the indicator, the numerator, and the denominator. Recommended tables that can be made using other data are shown. Finally, we present any notes that we think are important to understand the data presented. On pages 2 and 3 of a given Rate Tab, we show the same rate-based data for the other race/ethnic groups, as described earlier.

Comparing the state and local rates and confidence intervals on Table 2, from start to end of period, we see that the local rate and its upper confidence intervals are always below the state rate. This allows us to conclude that the local rate was significantly lower than the state throughout the time period. In both cases, we also see that the rates appear to be rising. This leads us to wonder if the rise in rates is statistically significant. Is the rate of change the same for the jurisdiction and state? That is, do we have a trend, and if so, is it linear or curvilinear? How does the jurisdiction compare with the state?

DISPLAYING AND TESTING TRENDS

If rates are on the Rates Tab, as for our example, we display local and state rates over the period on the Graph Tab and show results of statistical tests for trends and rate differences. If the data permit 12 years of rates, as they do here, we also test for non-linear trends.

THE TREND GRAPH

Figure 7 shows the graph made using the rates from Page 1 of the Graph Tab for our example indicator. Depending on the number of events the data allow us to calculate, a given graph might have 6 or no points. Note that the graphs do not include confidence intervals, which would be inappropriate for a trend test. Here, we focus on the rate of change over time rather than within a given period such as a year.

Figure 7. Primary Cesarean Rate Trend Per 100 Eligible Deliveries Age 15 to 44

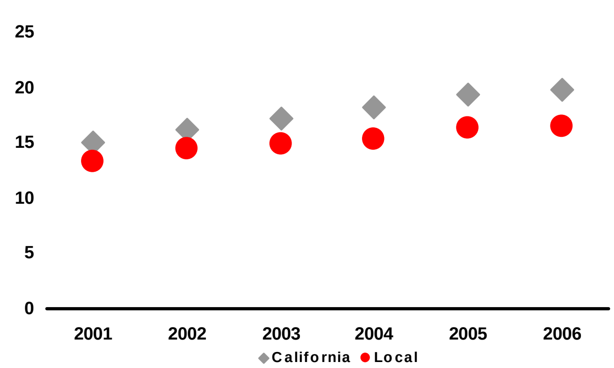


Figure 7 has 6 points, because the number of events was greater than 10 in all years. If the indicator had too few cases, the graph would be empty. Red dots (●) show the local jurisdiction rate and grey diamonds (◆) the state rate. When an indicator has a Healthy People (HP) 2010 performance objective, it is shown with a dashed blue line. For this indicator, the HP 2010 objective is 15 per per 100 low-risk deliveries.

STATISTICAL TESTS

We evaluated the indicator data on the rate tab two ways. First, we evaluated it to see if the trend we see is statistically significant. The emphasis here is on the rate of change over time, asking in essence if the local jurisdiction is changing at a rate similar to or different from the state and in what direction. Second, we tested if the local jurisdiction rate is significantly different from the state at the start and end of our time period. The emphasis here is whether local jurisdiction results are lower than, higher than, or the same as the state. Table 3 reports the results of these two types of statistical tests for our example: trend test and difference test.

Trend Test. Sometimes the "eyeball" test may make you think that significant linear trends are present when in fact the data are not linear or the trend is not significant. For example, the linear trend test may be non-significant because the data has some other shape like ∩ or ∪. When the data has another shape, it would be inaccurate to describe a trend as linear.

We used JoinPoint software to test for trends. When JoinPoint finds that one or more segments of a time period have slopes that are significantly different from the slope of the previous period or finds significant shifts in the intercept, it breaks the trend into segments. This means that JoinPoint found a bend, or change in the angle of the trend line or intercept that is statistically significant from the previous segment at P = 0.05 or less. If bends are found, JoinPoint defines the time-based segment and describes the slope and intercept during each period. Each time the segment slope changes, its intercept also changes.

Because this databook had only 6 years of data, it was not possible to test for bends. Thus, we report the simple linear model. If the numbers of local cases were too few to test 6 periods, JoinPoint did not test for a trend.

Table 3. Primary Cesarean Rate Trend Regression Results Per 100 Eligible Deliveries Age 15 to 44

		Intercept		Slope			
Level	Date Range	Est.	Std. Err	Est.	Std. Err	P-Value	Sig?
State	2001-2006	15.15	0.14	1.00	0.05	0.000	Yes
Local	2001-2006	13.90	0.19	0.65	0.06	0.001	Yes
	Different?					0.000	Yes
State Avg	2001-2003	16.13	0.03				
Local Avg	vs State	14.58	0.07			0.000	Yes
State Avg	2004-2006	19.18	0.03				
Local Avg	vs State	16.50	0.08			0.000	Yes

State Trend. The first data row in the Level column contains the word "State". The "Date Range" column shows one time interval. If a simple linear model was justified, one line of State results shows, and the Date Range column shows the 6-year range.

For each trend, the next column sets show the intercept and its standard error, the slope and its standard error, and the P-value associated with the slope. In the last column, we identify by "Yes" or "No" if the slope is significantly different from zero at P = 0.05 or less.

JoinPoint accepted the hypothesis that the best fit for the state trend is linear. From 2001 to 2006, the state rose at a rate of 1.0, as shown by the P-value of 0.000.

Local Trend. The first column contains the word "Local". In all other respects reporting of the local trend is like the state trend discussed above. For our example, JoinPoint found the local trend (0.65) was statistically significant (P-value = 0.001). The last column summarizes the "big picture": "Yes" means the trend is significant at P = 0.001.

If the local jurisdiction has too few cases to calculate trends, we show the text "Too few cases", and the rest of the table is blank.

Difference of Slopes Test. If JoinPoint accepts a linear model for both the State and jurisdiction, we test to see if their slopes are significantly different from each other. That is, we test the null hypothesis that the local and state trends are equal, assuming the data are independent and had a normal distribution. In essence, we perform a T-test on the slopes.

Table 3 shows that both the state and local jurisdictions had significant linear trends. When both trends are linear, line 3 of the "Level" column is blank and the "Date Range" column contains the word "Different?". The P-value is from the test that the local slope equals the state slope over the 6-year period.

Again, a "Yes" or "No" indicates whether the P-value is statistically significant. In this case, both trends are statistically significant, and the local rate of change is statistically different from the state rate of change. In any circumstance where the difference of slopes test is not statistically significant, report the state rate, since the local rate is not different from that, and the state rate has more power. Only when the two trends are significantly different should the local trend be reported in favor of the state trend.

Difference of Rates Tests. The trend tests above describe the rate at which outcome indicators are changing and their direction (improving, getting worse, or no change), and, if the trends are simple linear, whether the local jurisdiction is changing at the same or a different rate than the state. But these do not answer a question of central importance to most jurisdictions: Did they do better, the same as, or worse than the state as a whole? To approach this question, we did difference of rates tests, comparing the local jurisdiction to the state for the first three years and the last three years of the trend period. These results also are shown on the graph tab, with Tables 3 containing the example results.

State Average in First 3 Years. The first column shows "State Avg", and the Date Range column identifies the first 3 years in the period. The three-year average state rate and its standard error are displayed in the Intercept Estimate and Standard Error columns. In the first three years of the example period for Table 3, the average state rate was 16.13 primary cesareans per 100 eligible deliveries to women age 15 to 44. Notice that the jurisdiction standard error is wider than the state, since the jurisdiction is smaller.

Local Average in First 3 Years and Comparison to State. This is located on the line after the State Average. The first column contains "Local Avg" and the Years column contains the words "vs State". The three-year average local rate and standard error are displayed in the Intercept Estimate and Standard Error columns. In the first three years of the trend period for Table 3, the local jurisdiction rate was 14.58 primary cesareans per 100 eligible deliveries to women age 15 to 44.

The "P-value" column shows the P-value for the test that the state and local 3-year rates are the same. "Yes" indicates that the P-value is less than 0.05 and the state and local rates are significantly different. "No" indicates that they are not significantly different. The example local jurisdiction had a statistically lower primary cesarean rate than the state during the first 3-year period.

State Average in Last 3 Years. Like first 3 Years described above, with the State as a whole having a rate of 19.18 primary cesareans per 100 eligible deliveries to women age 15 to 44.

Local Average in Last 3 Years and Comparison to State. This is like the first three years described above, with the local jurisdiction having a rate of 16.5 primary cesareans per 100 eligible deliveries to women age 15 to 44. The "Yes" in the last column, and the P = 0.000 indicate that the local jurisdiction had statistically lower rates than the state during the last three years in the 6-year period.

CONCLUSION

The local rate of primary cesareans per 100 eligible deliveries to women age 15 to 44 rose linearly at the statistically significant rate of 0.65 per 100 eligible primary cesareans during the period 2001-2006. Similarly, the state's rate rose at a rate of 1 eligible primary cesareans. The local rate was significantly below the state rate at the start and end of the period.

In this jurisdiction, eligible women age 15 to 44 were less likely to have a primary cesarean than the state average.

Readers with a non-statistical background will find it most helpful to focus on the last column of the trend results table. If it says "Yes," the trend is significant at P = 0.05. Those who would like a statistical refresher may wish to review the FHOP monograph, "Do We Have a Linear Trend?" It is available on the FHOP website at: http://www.ucsf.edu.

APPENDIX A: CALCULATING ANY PATIENT SAFETY INDICATOR WITH RISK ADJUSTMENT

CALCULATION OF "ANY PATIENT SAFETY INDICATOR"

The "Any Patient Safety Indicator" is defined as the combination of any of the following AHRQ patient safety indicators:

1: Complication of anesthesia
2: Death in low mortality DRGs
5: Foreign body left in during procedure
7: Infection due to medical care
18: OB Trauma – Vaginal delivery with instrument
19: OB Trauma – Vaginal delivery w/o instrument
20: OB Trauma – Cesarean delivery

Another patient safety indicator, ANYADV, focused on ICD-9 codes that are defined adverse events. In these, risk is at the facility level and not the patient level, e.g., giving insulin to a patient who does not have diabetes. ANYADV was calculated by searching over all diagnoses and procedures using the CCS classifications for ICD-9 defined complications of device or procedure, and E-codes for adverse effects of medical care, medical drugs, or accidents in hospital. Reabstraction studies have found that these tend to be under-reported, but those that are recorded did happen.

Each of these indicators was calculated for each patient using AHRQ software that results in flag variables with values 0, 1 or missing. An indicator was missing if the patient was not in the risk pool for that indicator. A given patient was in the risk pool for only one of the 3 indicators 18, 19 and 20, because these are defined based on delivery mode.

A patient was in the numerator, ie counted as having "Any patient safety indicator" if they were "true" (value=1) for any of the above components.

CALCULATING PROBABILITY OF SINGLE INDICATORS

The probability of occurrence of indicators 1, 7, 18 and 19 were calculated using SAS code from the AHRQ program PSSASP3.sas. This takes into account the patient’s age and DRG category, applying weighting factors (regression coefficients) for comorbid conditions estimated from a national database and supplied with the AHRQ programs.

The probability of occurrence of PSI 2, 5, and 20, and "Any Adverse" were obtained from the overall rate of occurrence in the California delivery population. They are as follows

PSI 2:	366/3466825 = 0.0001055721
PSI 5:	129/3475593 = 0.0000371160
PSI 20:	2866/893750 = 0.0032067133
Any Adv:	28268/3475593 = 0.0081332883

These probabilities were used in every case, not varying due to patient characteristics. We took the maximum probability over all the pooled indicators.

APPENDIX B: OTHER STATISTICAL ISSUES

The entire process of creating the Databooks is macro driven using SAS. The process starts by summarizing the indicator data and the appropriate denominator data to the geographic level of interest (state, county, super region (e.g., Bay Area) or sub-region (Berkeley, Long Beach, Pasadena, LA County Service Provider Areas). We calculate rates, feed the numerators and denominators into JoinPoint, bring the results back into SAS, and output the results directly into preformatted Excel template files.

We use JoinPoint to estimate linear trends for the jurisdiction and state and to test whether the resulting slope for each trend is significantly different from zero.[32] [33] The Statistical Research and Applications Branch (SRAB) of the National Cancer Institute developed JoinPoint as one among a set of new statistical methods and associated software tools for the analysis and reporting of cancer statistics. This group of powerful shareware statistical packages is appropriate for the analysis of any population-based data.[34] In this set of software, JoinPoint was developed explicitly to estimate linear and curvilinear trends.

JoinPoint takes trend data and fits the simplest trend model that the data allow. The user supplies the minimum and maximum number of joinpoints. The program starts with the minimum number of joinpoints (e.g. 0 joinpoints, which is a straight line, or a standard trend test) and then tests whether more joinpoints are statistically significant and must be added to the model (up to that maximum number). This enables the user to test if an apparent change in trend from one period to another is statistically significant. The tests of significance use a Monte Carlo Permutation method.

Models may incorporate estimated variation for each point (e.g. when the responses are age adjusted rates) or use a Poisson model of variation. In addition, models may be linear on the log of the response (e.g. for calculating annual percentage rate change). The software allows viewing one graph for each joinpoint model, from the model with the minimum number of joinpoints to the model with maximum number of joinpoints.

Joinpoint uses a complex algorithm to decide whether to add a bend ("join point") to a simple linear model. For each line segment, or for the whole time period, Joinpoint tests whether the slope is equal to zero (i.e. the line is flat). When calculating the standard error of the slope of a segment it ignores points at the bend, which reduces the effective sample size when calculating the standard errors of the slopes. Consequently, Joinpoint tests comparing the slopes to zero are quite conservative.

Joinpoint program options we used to calculate trends are: 1) input numerators and denominators, 2) test for bends at whole years, 3) use a minimum of two years between bends and between a bend and either end of the data, 4) test for a maximum of 2 bends, 5) fit a linear (not log-linear) model with uncorrelated errors.

We decided to use the single line model unless one or more line segments had a slope significantly different from zero. If both the local and state data used a simple linear model, we tested the equality of the two slopes by using the estimates and standard errors reported by Joinpoint. The standard error of the difference was calculated as the square root of the sum of the squared standard errors.

In calculating state and local three-year rates, we used the total of the numerators and the average of the denominators over the 3 years. Then we divided the resulting rates and confidence limits by 3. In this calculation we used the same methodology as used to calculate 1-year rates and confidence intervals displayed on the rates table, namely the Wilson approximation method. The 95% confidence intervals were converted into an estimated standard error by dividing the width of the confidence intervals in half and then dividing by 1.96. We tested the equality of the two rates using the estimated rates and standard errors.

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[21] Note that the minimum numbers we used are smaller than those suggested in FHOP's "Small Numbers Guidelines," because the focus is on longitudinal trends rather than one-year comparisons, and the statistical tests we used are based on counts rather than rates.

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