## A Retrospective Study of the Relationship Between Hospital Regulatory Agency Variations and Opioid Mortality Rates, 1999-2014

Ethan Bernstein<sup>1</sup> and Cheri Chisesi<sup>1</sup>
<sup>1</sup>Saucon Valley High School, Hellertown, Pennsylvania

#### **Summary**

Mortality from opioid abuse has risen dramatically in the United States over the last two decades and has become a national health crisis. The majority of hospitals in the United States receive accreditation by the Joint Commission on Accreditation of Healthcare (JCAHO). In July 2000, JCAHO released major revisions to its standards of care regarding pain evaluation and treatment. A common opinion is that JCAHO's early 2000's pain management standards are to blame for the opioid epidemic. The main objective of this research was to study opioid mortality over time in order to understand the contribution—or lack thereof—of hospital regulation regarding opioid usage. The following hypotheses were developed: (1) average death rates due to opioid overdose will be significantly different when comparing states grouped by hospital accreditation mix and (2) pre-post change in average death rates due to opioid overdose will be significantly different between states grouped by hospital accreditation mix.

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## Introduction

Over the last twenty years, mortality from opioid abuse has increased drastically. Over a half million Americans died from drug overdoses between the years 2000 and 2014 (1). The rate of death from prescription and illicit opioid drug overdoses increased 200% in the United States between 2000 and 2016. In 2014, 47,055 drug overdose deaths (14.7 per 100,000 individuals) occurred in the United States, a 1-year increase of 6.5% from 2013 (2). More people died from drug overdoses in 2014 than in motor vehicle accidents, and opioid overdoses have become the leading cause of accidental death (2). While the age-adjusted rate for deaths from prescription opioids have leveled somewhat over the last few years, there has been a five-fold increase in the age adjusted mortality rate from heroin in the United States from 2002-2014 and a tripling since 2010 (2). The

trend has been termed an epidemic akin to an infectious disease.

Agencies at the federal and state levels of government have begun to react to the crisis. In 2011, the White House put forth a plan with a \$1 billion-dollar budget to partner federal agencies with states (3). In 2015, The Secretary of Health and Human Services presented the Secretary's Opioid Initiative which was focused on changing prescribing practices and making opioidreversal drugs and opioid addiction treatment more available (4). In 2016, the Centers for Disease Control and Prevention (CDC) released its' CDC Guideline for Prescribing Opioids for Chronic Pain which was backed by the the United States Surgeon General (5, 6). At the state level, programs were made available to physicians, such as the Pennsylvania Prescription Drug Monitoring Program, which allows individual physicians to search a database for each patient's previous opioid outpatient prescriptions when writing a first prescription for an opioid analgesic or whenever there is a clinical concern the patient may be developing an addiction (7). The Centers for Medicare and Medicaid Services (CMS) introduced new requirements that would establish opioid utilization management, and Congressional bills were introduced for prevention and treatment via the Comprehensive Addiction and Recovery Act and the Opioid and Heroin Epidemic Emergency Supplemental Appropriations Act (8).

Up until 2008, CMS had authorized two accreditation programs to survey hospitals: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Healthcare Facilities Accreditation Program (HFAP). The majority of hospitals in the country are accredited by JCAHO but HFAP has moderate penetration in some parts of the country. In 2008, Det Norske Veritas Healthcare was also approved by CMS, making it the third accreditation organization in the United States. JCAHO continues to regulate the majority of hospitals in the United States.

In July 2000, JCAHO released major revisions to its standards of care regarding pain evaluation and treatment (9). It made those standards mandatory for institutions to remain compliant and gain accreditation with JCAHO effective January 1st, 2001. One hypothesis that has become very popular in both the medical and legislative communities is that pain management standards and guidelines released in 2001 by JCAHO inadvertently caused the opioid epidemic via the law of

unintended consequences (11 - 13). The theory insists that these new 2001 JCAHO standards instructed hospitals to repetitively ask patients about pain and to prioritize treatment of pain, which directly led to the opioid epidemic. This theory has been popularized, particularly on the internet via physician blogs, but also in more respected news outlets and scientific journals. Manchikanti et al. 2012 placed the blame for the current epidemic on new pain regulations by JCAHO, the recognition of pain-relief rights, numerous oversight organizations backing opioid usage, and advertising by pharmacies (13). Lucas et al. 2007 concluded that the present assessment of pain by computers focuses too heavily on under-medicating while ignoring over-medicating (14).

In April 2016, a letter was sent to the CEO of Joint Commission signed by a group of leaders from multiple state health department, patient advocacy groups, and medical organizations asking that JCAHO reconsider its pain standards (15). Will Humble has suggested that the cause of the opioid crisis can be attributed to both the phrase "Pain as the 5th Vital Sign" and its adoption by the Joint Commission on Accreditation of Healthcare Organization's Standards Related to the Assessment and Treatment of Pain (16). Other prominent writers have proposed that JCAHO is partially at fault for the opioid epidemic and suggest that Congress must force JCAHO officials to go on trial and recognize their blame for the opioid crisis (17, 18), On May 8th, 2012, the United States Senate Committee on Finance sent official inquiry to the president of JCAHO questioning JCAHO's role in the opioid epidemic (19). JCAHO has been blamed as the primary cause of the current opioid epidemic due to their "Pain as the fifth vital sign" initiative. (20).

On April 18th, 2016, David W. Baker, the Executive Vice President of Healthcare Quality Evaluation of JCAHO, released the Joint Commission Statement on Pain Management defending JCAHO against criticisms that its standards in the early 2000s were a major contributor to the opioid epidemic. It was an attempt to dispel what he called "misconceptions" about the link between the JCAHO standards and the epidemic (21). Baker stated that prescribing rates were on the rise long before JCAHO released its pain-management standards. As a follow-up, JCAHO released a downloadable poster titled "Common myths about The Joint Commission pain standards" on their website (22). In both documents, the rebuttal was made against the criticism of JCAHO opioid prescription statistics using data extracted from the US Retail Pharmacies IMS Health and IMS Health National Prescription Audit. The data showed an uptick in opioid prescriptions occurring from 1997 to 1998, which Baker states refutes the connection between the JCAHO pain standards and the prescription opioid epidemic (23) (Figure 1).

The CDC has analyzed multiple causes-of-death mortality data from the National Vital Statistics System to track drug overdose deaths nationally at the state level from 2000-2014. Opioids are the main drivers of overdose deaths. Ohio was one of the five highest

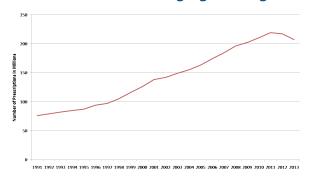


Figure 1. Number of opioid prescriptions written in the United States yearly from 1991 to 2013. Plotted with the number of opioid prescriptions in millions as a function of year which shows that the number of opioid prescriptions in the United States have been rising steadily from 1991 to 2013.

states with regard to drug overdose death rates in 2014 (2). Also, Ohio, along with Indiana and Michigan, all had statistically significant increases in drug overdose rates between 2013 and 2014. Conversely, Delaware, New York, and New Jersey did not have a statistically significant change in age-related mortality rates between 2013-2014 nor were they in the group of five states with the highest drug overdose death rate in 2014 (2). Based on this data, a question arose: would statistical data show that state opioid overdose deaths did not change based on the penetration of alternative accreditation organizations over the period of time since JCAHO released its pain standards?

The main objective of this research was to study the opioid mortality rates over time and assess the contribution of hospital regulation to overdose deaths. The following hypotheses were developed: (1) there would be a statistically significant difference in the average death rates due to opioid overdose when comparing states grouped by hospital accreditation mix for the years 2002 – 2014; and (2) there would be a statistically significant difference in the pre-post change values comparing average death rates due to opioid overdose between states grouped by hospital accreditation mix in year 1999 versus year 2003.

#### Results

We decided to choose a group of three states with the highest HFAP accreditation percentage and three more states with the lowest HFAP accreditation percentage to limit the amount of data we had to deal with and to compare the most dissimilar groups with regards to accreditation (Table 1).

State	Acute Beds Total	HFAP Beds Total	HFAP Beds %	
New York (Uniform)	57,457	610	1.06%	
New Jersey (Uniform)	20,772	526	2.53%	
Delaware (Uniform)	1939	0	0%	
Michigan (Mixed)	23,567	2935	12.45%	
Ohio (Mixed)	28,286	2782	9.83%	
Indiana (Mixed)	16,153	5897	36.50%	

**Table 1.** Total hospital beds per state including total acute care beds and percentage of the beds accredited by HFAP per state.

Two groups of three states, each with a significant mixture of accrediting agency regulation ("Mixed Block") and low percentile of non-JCAHO accreditation regulation ("Uniform Block") respectively, were selected in order to test our hypotheses. The Mixed Block of states had 17.08% accreditation by HFAP while the Uniform Block of states had .01% accreditation by HFAP. We noted a *p*-value of 0.048, indicating there was a statistically significant difference between the Uniform and Mixed groups with regards to accreditation mix. Overdose death rate data from opioids for each of the states in the two blocks was obtained from the CDC Wonder Online Database (Table 2).

In order to determine whether the differences in state hospital accreditation percentages were superficial or statistically different, a statistical analysis was performed using a simple two-sample t-test. We set our alpha level at .05. We first plotted the individual states age-adjusted mortality rates and then plotted mean age-adjusted mortality rates over time for our state groups comparing uniform JCAHO accreditation vs. the mixed accreditation (Figure 2,3). In order to determine if the differences in mortality rates were only superficial or

Year	New York	New Jersey	Delaware	Uniform Mean	Michigan	Ohio	Indiana	Mixed Mean
1999	3.2	3.8	4.1	3.7	1.2	1.5	.8	1.167
2000	2.6	4.1	3.7	3.467	1.8	2.2	.7	1.567
2001	3.2	4.6	4.5	4.1	1.9	3.0	1.1	2
2002	2.9	5.6	6	4.833	2.3	3.7	1	2.333
2003	3	5.1	4.5	4.2	2.5	3.2	2.1	2.6
2004	2.4	3.6	4.2	3.4	3.5	4.5	2.2	3.4
2005	2.9	5	3.5	3.8	4.8	4.9	2.6	4.1
2006	5.2	4.3	4.5	4.667	6	5.6	2.8	4.8
2007	5.2	3.9	5.1	4.733	5.1	6.2	3.9	5.067
2008	5.6	3.8	7.7	5.7	6.5	7.2	5	6.233
2009	5.4	.7	9.3	5.133	7.5	5.9	5	6.133
2010	5.4	4.2	12	7.2	7	10	4.5	7.167
2011	6.8	5.1	12.6	8.167	7.5	11.2	5.6	8.1
2012	7.6	6.8	9.2	7.867	7.1	12.3	5.9	8.433
2013	8.3	7.6	12.8	9.567	9.4	14.5	5.7	9.9
2014	8.6	8.2	13.9	10.233	10.9	19.1	7.3	12.433

**Table 2.** Data for annual age-adjusted opioid overdose mortality rates per 100,000 for individual states, including uniform and mixed state group means 1999 to 2014.

if they were statistically different, a statistical analysis was performed again using a simple two-sample t-tests for each year of data (Figure 4). The t-test was used to compare age-related mortality rates from all opioids between the six states in the Uniform versus Mixed state groups for each year between 2002 and 2014. The study period was chosen under the assumption that in the years 2000 and 2001 the JCAHO standards were not made mandatory and may not have been fully implemented. As such, 2002 was used as a starting point. 2014 was the most recent data available to us when we started this research project. The p-values for each t-test of opioid mortality rates from 2000 to 2014 were non-significant, meaning that the rate of mortality due to all opioids is not statistically different in any of the individual years between the Uniform and Mixed Groups.

We also compared age-adjusted opioid overdose death rates for the Uniform vs. Mixed groups for years 1999 and 2003 to compare pre-post change values. We

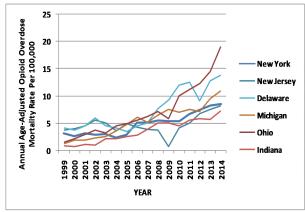


Figure 2. Annual age-adjusted opioid overdose mortality rates per 100,000 by individual state from 1999 to 2014. Plotted with the number of age-adjusted opioid overdose mortality per 100,000 as a function of years 1999 to 2014. A separate plot was made for each state and allows comparison between the individual states in regard to opioid overdose mortality rates.

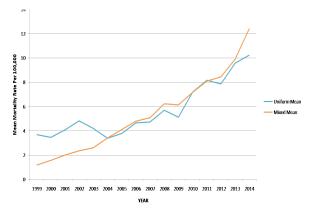


Figure 3. Mean mortality rates due to opioid overdose per 100,000 uniform vs. mixed state groups from 2002 to 2014. Plotted with the number of age-adjusted opioid overdose mortality per 100,000 as a function of years 1999 to 2014. A separate plot was made for the mean opioid mortality rate per 100,000 for both state groups and allows comparison between the two groups in regard to opioid overdose mortality rates

chose 1999 because it was prior to the initial JCAHO revision of pain evaluation and treatment standards of care in 2000. We chose 2003 because JCAHO did not make its new pain standards mandatory until January of 2001 and we felt that full adoption of the standards by JCAHO-accredited institutions might have taken another 1-2 years. We would have preferred to obtain a multiyear average rate (1995-1999, for instance) for each state from prior to the JCAHO pain standard adoption to compare to a multi-year post-adoption state rate, but data prior to 1999 was not available. We subtracted the 1999 rate from the 2003 rate for each state to obtain a pre-post change value. We performed statistical analysis comparing the groups pre-post change values using a simple two-sample t-test. We set our alpha level at .05. Our statistical analysis of the pre-post change value had

a two-tailed *p*-value of 0.39. Our statistical analysis of the mortality rates and the pre-post change values do not offer compelling evidence that the JCAHO policies changed the mortality rates due to opioid overdose.

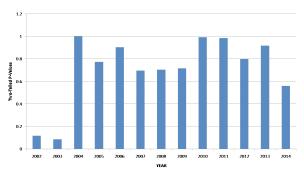


Figure 4. *P*-values of t-tests performed comparing ageadjusted mortality rates per 100,000 between mixed and uniform state groups from 2002 to 2014. The figure includes relationship of *p*-values to alpha level. The figure allows for visualization of statistical significance or lack thereof over time.

#### **Discussion**

Our data shows that that hospital accreditation by JCAHO probably was not the primary influence driving the opioid drug overdoses in the small state sample we analyzed. The idea that factors beyond JCAHO contributed to opioid mortality has been discussed in other studies. An article published in the Wall Street Journal in 2012 by Catan and Perez looked carefully at the origins of the opioid epidemic (24). Their thoughtful look at the issue identified multiple causes of the epidemic. They did identify JCAHO's standards and guidelines as a possible early influencer of the epidemic. However, they also discussed a host of other possible players, which included underpowered scientific papers and landmark consensus statements supporting the safety of opioids.

One of the seminal statements, deemed by some to have helped launch the opioid epidemic, was a hundred-word letter to the editor published in the 1980 New England Journal of Medicine written by Jane Porter and Hershel Jick of the Boston Collaborative Drug Surveillance Program at Boston University Medical Center. It reported that less than one percent of patients at Boston University Medical Center who received narcotics while hospitalized became addicted (25,26). A study published in 1986 in Pain concluded that in noncancer patients, opioids can be safely and effectively prescribed to selected patents with relatively little risk of producing the maladaptive behaviors that define opioid abuse. The study was based on 38 cases (27). They also named persuasive physician speakers who had influence through their role in prominent pain societies and foundations and pain societies and foundations during their 5th vital sign campaign as culprits in the progression of the opioid epidemic. Another possible factor discussed was the Federation of State Medical Boards' support of increased opioid prescribing. The Federation made

recommendations to protect over-prescribers (a 1998 recommended policy) and sanctions against under-prescribers through pressures on individual state boards (policies developed in 2004). Catan and Perez also pointed out the pharmaceutical company misbranding of opioids and influence on policies and guidelines being published by the Federation of State Medical Boards and JCAHO, respectively (24).

Other possible influencers that we've identified in the literature are legal articles promoting undertreatment of pain as a case for medical malpractice and medical malpractice cases against physicians for undertreatment of pain. One example of a medical malpractice suit was Bergman v Edem Medical Center in which a doctor was found liable in a lawsuit over pain management (28 - 30). Furthermore, the Veteran's Administration's adoption of pain as the fifth vital sign in 2000 is a factor. With these hospitals evaluating pain in 5.69 million new patients, the use of opioids was certainly increased to ensure positive pain evaluations. The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), a patient satisfaction survey required by CMS, is an attributor to the crisis because this survey has a pain component that may have pressured hospitals and hospital administrators to encourage more aggressive pain management. Lastly, generational changes in the national culture itself could be an influencer in pain perception. Over time, a certain amount of pain may begin to be perceived as more severe or less severe than the previous generation. Post hoc ergo propter hoc is latin for "after this, therefore because of this", which refers to an error in statistical logic in which an event that follows another is thought to be a consequence of the initial event. The opioid epidemic is a complex nationwide problem that cannot be blamed on one entity or source.

There are some limitations to this study. important limitation to acknowledge is that we only studied two small groups of states. We chose them based on the percentage of HFAP accreditation. However, by doing this, we allowed our two sample groups to be isolated from one another regionally. The Mixed group is primarily a Midwest regional group of states and the Uniform group is primarily an east coast regional group. This could have had an impact due to subtle cultural differences between the populations in the two regions. For instance, our two groups of states may have disparate percentages of Medicaid-insured populations. Adolphsen theorized in his National Review article that states with a large Medicaid-expansion program have seen a higher rate of opioid abuse due to medicaid enrollees access to prescription drugs via the Medicaid drug benefit card (31). He referenced several examples. First, he mentioned that CDC studies have shown that the Medicaid population has at least a twofold higher prescribing rate for opioids than non-Medicaid enrollees. Second, a study of Washington State opioid abuse showed that Medicaid enrollees were 5.7 times more likely to have opioid-related mortality than non-Medicaid enrollees (32). Most interestingly, he

specifically highlighted the seven states with the highest drug-overdose death rates, which included Ohio, and noted that all seven were in the group of thirty-one states that expanded Medicaid through the Patient Protection and Affordable Care Act. He went on to state that Ohio enrolled more than seven hundred thousand adults via Medicaid expansion and in 2017 is likely to have more drug overdose mortalities than the entire country did in 1990 (31). We would suggest that future investigators consider studying all fifty states from 1999 to most current year available.

Another limitation of the study is that we used current hospital accreditation data from HFAP's website. It is entirely possible and likely that some hospitals during the 2002-2014 reporting period changed accreditation from JCAHO to HFAP or vice versa. One would assume that most hospitals do not change accreditation frequently due to the large internal infrastructure that develops around following JCAHO vs. HFAP guidelines, but isolated instances of mid-stream changes are likely. Obtaining year-by-year data from each hospital with regards to accreditation would be an ideal approach for future studies.

Another weakness in the study is the limited percentage of HFAP accreditation in any one state. A more convincing argument could have been made if a few states had a majority of hospital beds accredited by HFAP. Another weakness in our study is that we did not use additional opioid mortality data that has become available in recent years. Additional studies should incorporate this data to strengthen the conclusions. Despite these limitations, this paper displays evidence that the blame for the opioid epidemic should not be placed on JCAHO.

#### **Methods**

Data was obtained for each state regarding ageadjusted opioid overdose mortality rates, acute care bed numbers, and individual hospital accreditation type for the 2002-2014 period. The total number of acute care hospital beds for every state in the United States was obtained from the American Hospital Directory website (33). Every hospital in the United States that is currently accredited by HFAP was identified on the Healthcare Facilities Accreditation Program website (34). Acute care bed totals for individual hospitals regulated by HFAP were cross-referenced with the total state acute care bed data to develop a percentile of HFAP regulation by bed per state. We showed the difference in accreditation mixes by using a t-test (35). A t-test was also used to compare age-adjusted mortality rates for each year due to opioid overdoses between our two groups of states using 2002-2014 data. A t-test was used to compare the pre-post change values comparing the Uniform and Mixed groups of states between 1999 and 2003.

Statistical analysis was performed using VassarStats software (Vassarstat.net).

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