Evaluation and Cost-Benefit Analysis of the Kentucky Decedent Controlled Substance Testing Law [KRS 72.026]

April 2017

Dana Quesinberry[a], Michael Singleton[a], Julia Costich[a], Terry Bunn[a], Sarah Hargrove[a], William Ralston[b], James Pollard[c]

[a]Kentucky Injury Prevention and Research Center, University of Kentucky, as bona fide agent for the Cabinet for Health and Family Services, Kentucky Department for Public Health

[b]Kentucky Office of the State Medical Examiner

[c]Kentucky Coroners Association

Table of Contents

Executive Summary

In 2012, Kentucky was in the midst of a mounting prescription drug overdose epidemic. Between 2000 and 2010, Kentucky's age-adjusted drug overdose mortality rates had almost doubled, and mortality rates continued to climb from 2011 to 2012 from 23.6 deaths per 100,000 persons in 2011 to 25 deaths per 100,000 persons in 2012. During this period, knowledge of the controlled substances involved in overdose deaths was limited: in 2011, only 70% of drug overdose death certificates listed the specific drug or drugs involved in the deaths. In June 2012, the Kentucky General Assembly, in special session, passed an omnibus bill to address the prescription opioid epidemic, House Bill 1 (HB1). Among other provisions, HB1 included a controlled substances testing law (CSL) to improve surveillance of fatal drug overdoses through mandated toxicology testing in investigations of deaths where no other cause of death was determined. In 2015, legislation was passed expanding the controlled substance testing mandate to all deaths that the coroner is required to investigate.

Kentucky Drug Overdose Death Investigations

Drug overdoses are one of many types of deaths that are required by law to be investigated. These investigations are conducted in a complex system of elected county coroners and state-employed medical examiners. The position of coroner is a county-level office established by the Kentucky Constitution. Coroners have a statutory duty to investigate certain cases, including drug overdose deaths. As part of those investigations, the coroner can request that an autopsy be performed by the State Medical Examiner. The Office of the State Medical Examiner has four regional sites staffed with forensic pathologists. In addition to autopsy services, the State Medical Examiner office subsidizes coroner toxicology testing by an independent laboratory.

Coroner toxicology testing utilization (CTU)

Coroner toxicology testing utilization (CTU) in coroner-certified, non-autopsy (CC-NA) deaths from all causes increased steadily from 16.6% in 2010 to 20.4% in 2014. This represents a statistically significant increasing trend in CTU ($p<0.0001$). While there was not a statewide increase in CTU following implementation of the CSL in 2012, localized increases occurred after CSL implementation in Fayette and Warren Counties, and in the Kentucky River Area Development District (ADD), followed by localized increases in other ADDs 7 to 14 months after implementation. These changes may have been due to the CSL, or may have been associated with concurrent coroner trainings and other outreach efforts to educate coroners about the requirements of the CSL.

Specificity of drugs (SDR)

There were 6,267 coroner-certified drug overdose (CCDO) deaths from July 2010 through June 2016. The percentage of CCDO deaths in which at least one specific drug was reported on the death certificate increased significantly from 69.2% in the second half of 2010 to 80.6% in the first half of 2016. The was a statistically significant increase of 6.5 percentage points

immediately following implementation of the CSL in July 2012, primarily in western Kentucky, which had the lowest SDR baseline prior to the CSL. In general, the timing and amount of change in SDR over the evaluation period varied depending on geographic area, predominantly due to differences in whether medical examiners were involved in death investigations.

The SDR trend in Kentucky was compared to trends in Alabama, Arkansas, Indiana, and South Carolina – states with medicolegal death investigation systems which share similarities with Kentucky's mixed medical examiner/ coroner system. No change in SDR was detected in any of the four comparison states during the period when Kentucky's CSL was implemented, which argues against any national, secular effect as a cause of the increase in mean SDR in Kentucky after implementation of CSL.

Overall, there was a strong statewide increase in SDR in KY from 2010 through 2016, particularly outside the large urban areas in Louisville and Northern KY. There have been a number of concurrent state-specific initiatives during this time aimed at increasing SDR in KY. They have clearly been successful, although it is difficult to attribute the increase in SDR solely to CSL implementation.

Coroner Survey

A survey of elected 120 Kentucky coroners was designed and implemented, with the assistance of a subcommittee of the Kentucky Coroners Association and the State Medical Examiner's Office, to understand the impact of CSL on drug overdose investigations, including autopsy and toxicology testing utilization, completion of death certificates listing specific drug involvement and cause, and coroner CSL-related training. When the cause of death was not known, 60.9% of respondent coroners used toxicology testing results to determine the underlying cause and contributing cause(s) of death. Where the suspected cause of death was a drug overdose, 80.4% responded that they always relied on toxicology results to determine the cause of death. Coroners reported that toxicology result use increased after passage of the CSL, indicating enhanced death investigation processes including both CTU and SDR. These perceptions may have been influenced by coroner CSL training. Coroners who had received CSL training reported higher use of toxicology results to complete the death certificates when compared to all coroner respondents. The state medical examiners facilitate the use toxicology results in the completion of death certificates with underlying and contributing causes of deaths by elected coroners. In Kentucky's decentralized death investigation system, the reliance on the state medical examiner's determination of cause of death validates the SDR listing on death certificates. Reported practical barriers to toxicology result use in SDR listing on death certificates centered less around the timeliness of the results and more on the complexity of poly-substance involvement on drug overdose death certificate completion.

Cost- Benefit Analysis

Kentucky's economic burden of drug overdose deaths is substantial: using the standard

statistical life valuation of $9 million,[i] the total cost was $9.171 billion in 2013 and $9.693 billion in 2014. A much more conservative estimate of an adjusted $1.2 million, based solely on anticipated earnings,[ii] yields costs of $1.228 billion in 2013 and $1.292 billion in 2014 and $1.556 billion in 2015.

While the decedent testing mandate is associated with an increase in the number of tests performed, the aggregate cost of drug-related tests actually declined when 2011 and 2015 totals are compared, reflecting price decreases for both the drug-related panel and the comprehensive panel. Thus, using the conservative estimate of $1.2 million as the value of a life saved, if a single life can be attributed to the decedent testing mandate, the cost-benefit ratio will be approximately 3:1. The host of intervening variables between increased testing and avoided overdose deaths impedes our ability to identify causation for the purpose of cost-benefit analysis.

Conclusion and Recommendations

Implementation of the CSL was associated with a statistically significant statewide increase in in SDR, and regional increases in CTU. Knowledge of the SDR involved in drug overdose deaths can be used to educate, inform, and improve interventions and policies to better target substance use disorder (SUD) treatment needs, SUD prevention efforts, controlled substance prescribing, and law enforcement investigations. The evidence from this evaluation of Kentucky's CSL may be used to inform SDR improvement legislative efforts in states with similar mixed medical examiner/ coroner death investigation systems. If mandatory decedent testing only saves one single life per year, it is highly cost-effective.

Overview of Report

Kentucky's General Assembly has undertaken several legislative initiatives to address prescription drug abuse (PDO) and drug overdoses (DO) in general. One provision of Kentucky's DO-related legislative package, enacted in 2012, is the requirement that coroners and medical examiners test decedents for the presence of drugs "where the cause of death is not known." (KRS 72.026(1), 2012). The provision was amended in 2015 to require testing of all decedents to determine "any controlled substances which were in the body at the time of death and which at the scene may have contributed to the cause of death" (KRS 72.026(1), 2015).

While toxicological testing may be conducted in other states as a matter of policy or practice, to the best of our knowledge, Kentucky is unique in codifying the decedent testing requirement into statute. It is thus appropriate to assess this law in terms of its impact on controlled substance testing volume, listing of the drugs involved in fatal overdoses, and its implementation costs as Kentucky and other states explore the impact of legal initiatives to reduce the burden of SUD and drug overdose.

The aims of this evaluation were to:

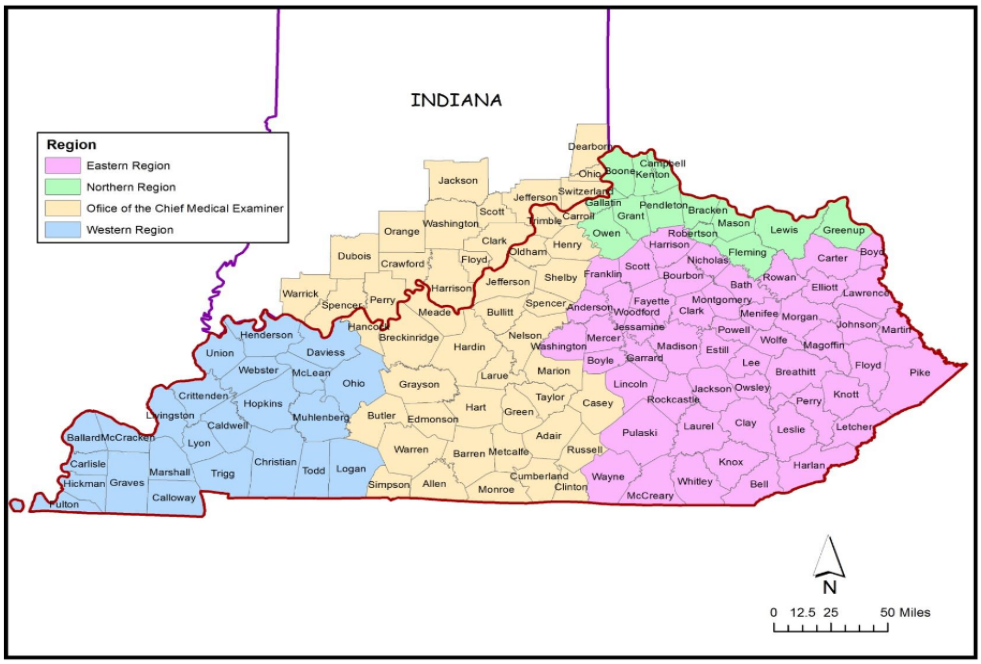
1. Assess the effect of the CSL on CTU by coroners. We hypothesized that the law would result in increased coroner CTU with a concomitant reduction in coroner utilization of autopsy ordering.
2. Assess the effect of the CSL on the SDR on death certificates. We hypothesized that SDR would increase as a result of increased use of CTU.
3. Assess the impact of the CSL mandate on coroners and identify the barriers and facilitators.
4. Assess the costs associated with CSL implementation for additional toxicology testing.

Kentucky Drug Overdose Death Investigations

Kentucky has a hybrid death investigation system made of up elected county coroners and state-employed medical examiners. The position of coroner is a county-level office established by the Kentucky Constitution. Eligibility to be an elected coroner is conditioned on residence in the county jurisdiction and being at least 24 years of age.[1] Coroners have a statutory duty to investigate mortality cases involving deaths that are violent, unattended, or occur under special circumstances.[2] Each of Kentucky's 120 counties is represented by an elected coroner.

The Office of the State Medical Examiner is a division of the Kentucky Justice & Public Safety Cabinet. The role of the State Medical Examiner is to assist coroners and law enforcement personnel in death investigations. Services provided by the State Medical Examiners include conduct autopsies to determine the manner and cause of death, identification of decedents, and the collection and interpretation of trace evidence.[3] The Office of the State Medical Examiner has four regional offices with service areas based on geographic location and population distribution. See Figure 1.

Figure 1. Service areas for the regional offices of the Office of the State Medical Examiner[3]



Both coroners and medical examiners play important roles in death investigations. Coroners have the legal duty to investigate suspected drug overdose deaths as delineated in Kentucky law. While coroners are legally charged with the duty to investigate, the Office of State Medical Examiner provides key services to aid in investigations including autopsy services and toxicology testing subsidies.

There are two points in the coroner investigation process where toxicology testing may occur.

Coroners may request an autopsy be performed by a state medical examiner and toxicology testing is usually performed as part of an autopsy (Figure 2). The medical examiner who conducts an autopsy produces an autopsy report with a recommended death certificate template since 2004 on a statewide basis. The coroner has discretion on the use the medical examiner's death certificate completion recommendations. The Chief Medical Examiner implemented a process in 2012 to examine the use of the recommendations which includes a review of the completed death certificate and subsequent discussions with the noncompliant coroners. Toxicology testing can also be requested by a coroner without a full autopsy request. In these cases, the coroner draws the necessary biological samples from a decedent and sends them to the independent toxicological testing laboratory contracted and subsidized by the State Medical Examiner. Generally, a coroner may only request a standard drug of abuse panel. A comprehensive panel, or specialized panel like the one needed to detect fentanyl analogues, must be approved by the Chief Medical Examiner. Additionally, the medical examiners may assist coroners with the interpretation of toxicology testing results and their implication in the manner and cause of death.

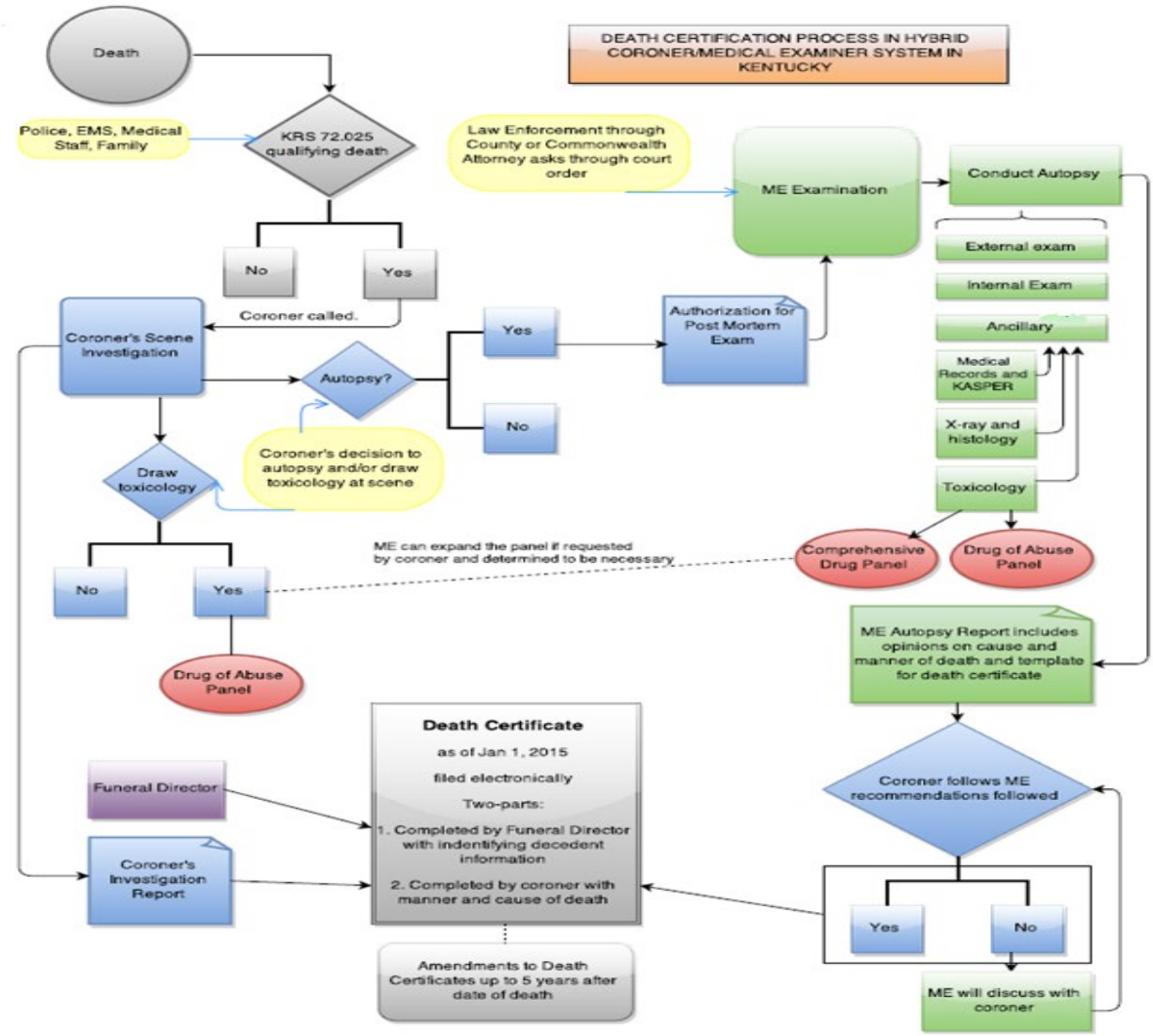
Under both testing scenarios, the ultimate authority to complete the death certificate lies with the coroners. This authority includes the determination of the cause and manner of death, the listing of underlying causes of deaths, and the listing of specific drugs involved in the death. The coroner may use all information available - from autopsy, toxicology testing, scene investigation, etc. – to complete the death certificate. Coroners may also complete Coroner Investigation Reports; however, there is no requirement to do so and completed reports are not collected in a central location.

The interactions of the coroners with the state medical examiners are controlled and influenced by both state law and policies established by the Chief Medical Examiner. In Kentucky, efforts to improve investigations of drug overdose deaths began when the Office of the Chief Medical Examiner sought accreditation with the National Association of Medical Examiners (NAME). NAME accreditation spurred improvements in death investigations in Kentucky. Prior to 2007, decedent toxicology testing was performed in the Kentucky State Police Forensic Lab. In 2007, the State Medical Examiner contracted with an independent laboratory to perform decedent toxicology testing. Also in 2007, the General Assembly incentivized coroner training participation through increases in coroner base pay based on training certification. (KRS 64.185(1)). New coroner training was implemented for all new coroners, and annual training requirements were mandated for deputy coroners. (KRS 72.415). The Office of the State Medical Examiner received NAME accreditation in 2002, and was reaccredited in 2008.

Efforts to improve death investigations have continued through improved coroner training content. The annual spring conference of the Kentucky Coroners Association was approved for continuing education credits. The State Medical Examiner has annually presented since year

???? on the use of toxicology testing results, the listing of involved drugs on death certificates, and on the drug overdose death investigations process in general. In 2011, coroners and their deputies were offered a special course on drug death investigations. By 2012, discussion of drug overdose investigations was regularly embedded in the required New Coroner Training course, the annual conference of the Kentucky Coroners Association, and other offered courses.

Figure 2. Kentucky's hybrid death investigation system with elected coroners and advisory State Medical Examiner



Statutory Controlled Substance Testing Mandate

In 2012, Kentucky was experiencing a mounting prescription drug overdose epidemic. As mortality rates were climbing in 2011 and 2012, the Kentucky General Assembly, in special session, passed an omnibus bill to address the prescription opioid epidemic, HB1. HB1

addressed pill mill ownership, framed opioid prescribing guidelines, and mandated controlled substance testing of certain decedents by coroners and medical examiners. The CSL provisions centered on the rising concerns that drug overdose deaths were undercounted and the involved drugs were not fully identified. (Warner et al., 2012). Codified in Kentucky Revised Statute § 72.026, the mandate required coroners and medical examiners to perform toxicology testing on decedents where the cause of death was not otherwise known. (KRS 72.026(1)).

Kentucky's General Assembly does not have an official legislative history. The intent of the mandate must be determined from the plain reading of the law, any amendments, and key stakeholder interviews. As originally drafted, the CSL Section 1 stated that

> Unless another cause of death is clearly established, in cases requiring a post-mortem examination under KRS 72.025 the coroner or medical examiner shall take a blood sample and have it tested for the presence of any controlled substances which were in the body at the time of death.
>
> KRS 72.026(1) (2012).

In a strict interpretation of this provision, toxicology testing of a blood sample is to be performed when the cause of death is not clearly established. Testing would not be required if, from other information, the coroner clearly established the death to be a drug overdose. The strict interpretation indicates that the intent is to identify drug overdoses as causes of deaths in cases where the cause of death was undetermined. Based on interviews with key stakeholders and quantitative assessment of the incidence of undetermined deaths, this strict interpretation does not reflect the true legislative intent.

In structured interviews with key stakeholders including the Director of Kentucky Office of Drug Control Policy and the Chief Medical Examiner, the intent of the legislation was to increase the use of toxicology testing by coroners and to increase the use of toxicology result reports to complete drug overdose death certificates with the controlled substances involved in the deaths. The later amendment supports this interpretation of the legislative intent. In 2015, the General Assembly expanded and clarified the mandate. The new language required testing as follows:

> In cases requiring a post-mortem examination under KRS 72.025, the coroner or medical examiner shall take a biological sample and have it tested for the presence of any controlled substances which were in the body at the time of death and which at the scene may have contributed to the cause of death.
>
> KRS 72.026(1) (2015).

Based upon this language in the amended provision, the intent is to capture the involvement of any controlled substance in drug overdose deaths.

Mandating testing is an attempt to ensure the availability of information on controlled substance involvement in drug overdose death. Assessment of specificity of drugs listed on death certificates will reflect the coroners' use of the controlled substance information learned from toxicology testing.

Additionally, a survey of elected coroners provided an assessment of the impact of the mandate on death investigations including identification of barriers and facilitators to implementation of the mandate.

Coroner Toxicology Utilization (CTU)

The CSL applied to deaths for which a cause of death could not be established based on routine coroner investigation (without toxicological analysis or autopsy). There was no method to identify those cases so a proxy set of cases was analyzed. The proxy set of cases was all coroner-certified deaths for which an autopsy was not requested.

Data sources

Death certificates were obtained from the Kentucky Department for Public Health, Vital Statistics Branch, for deaths occurring in Kentucky between 2010 and 2014. From 2010 through 2015, all toxicological testing in Kentucky – whether requested by a coroner or a medical examiner (ME) – was conducted by American Institute of Toxicology (AIT) Laboratories. Individual toxicology testing results were not available for evaluation analyses. To determine the use of toxicology results, coroner and ME invoice records from 2010 through June 2015 were obtained from the Kentucky Cabinet for Justice and Public Safety.

Death certificate- toxicology testing result data linkage

To determine whether toxicological testing was ordered for each drug overdose-suspected death occurring in Kentucky from 2010 to 2014, we linked the death certificate and toxicology result files using probabilistic data linkage (PRL) (Newcombe 1957; Fellegi and Sunter 1969; Clark 2004). PDL was used because errors (e.g. misspelling of names) and omissions on matching variables were expected, and because in general, death date and service date were not expected to be the same. Records were matched on decedent name, county of death, and date of death vs. service date (i.e. the date the test was run by AIT). PDL was implemented using LinkSolv version 9.0 (Strategic Matching Inc., Morrisonville NY).

For more details, see a full description of the methods in Appendix A.

Results

More than three-quarters (77.8%) of all deaths occurring in Kentucky from 2010 to 2014 were certified by physicians. The remaining 22% were split nearly evenly between coroners and deputy coroners. While the annual proportion of total deaths certified by coroners' offices was

consistent over this period, there was a shift in 2011 towards greater involvement of deputy coroners in death certification (Table 1). The total number of deaths certified by coroner offices ranged from a low of 9,241 in 2010 to a high of 9,927 in 2012.

Table 1. All deaths occurring in Kentucky, by certifier (2010-2014)

	Certifier			
Year	Coroner N (%)	Deputy coroner N (%)	Physician/Other* N (%)	Total N (%)
2010	6,277 (15.0)	2,964 (7.1)	32,508 (77.9)	41,749 (100.0)
2011	4,440 (10.5)	4,917 (11.6)	32,954 (77.9)	42,311 (100.0)
2012	4,339 (10.0)	5,588 (12.9)	33,402 (77.1)	43,329 (100.0)
2013	4,182 (9.7)	5,230 (12.1)	33,891 (78.3)	43,303 (100.0)
2014	4,342 (9.8)	5,499 (12.4)	34,648 (77.8)	44,492 (100.0)
Total	23,580 (10.9)	24,198 (11.2)	167,406 (77.8)	215,184 (100.0)

***** Few than 0.1% in this category were reported as "Other"

For drug overdose deaths, coroners have the responsibility for certification. Coroner offices certified 94% of drug overdose deaths between 2010 and 2014. Certification by deputies in drug overdose deaths is increased over time: in 2010 coroners certified 32% of drug overdose deaths in Kentucky compared to 62% in 2014 (Table 2). The decrease in physician/other certification of drug overdose deaths from 2010-2014 may reflect increased awareness of the certification responsibility training by the Office of the Sate Medical Examiner.

Table 2. Drug overdose deaths occurring in Kentucky, by certifier (2010-2014)

	Certifier			
Year	Coroner N (%)	Deputy coroner N (%)	Physician/Other* N (%)	Total N (%)
2010	595 (61.0)	313 (32.1)	68 (7.0)	976 (100.0)
2011	469 (44.9)	525 (50.3)	49 (4.7)	1,044 (100.0)
2012	430 (40.2)	581 (54.3)	60 (5.6)	1,071 (100.0)
2013	344 (34.1)	612 (60.6)	54 (5.4)	1,010 (100.0)
2014	355 (32.6)	673 (61.9)	60 (5.5)	1,088 (100.0)
Total	2,193 (42.2)	2,704 (52.1)	293 (5.6)	5,189 (100.0)

***** Few than 0.1% in this category were reported as "Other"

Table 3 examines autopsy utilization in coroner-certified deaths occurring in KY. Between 2010

and 2014, an autopsy was requested in 23% of all deaths certified by coroner's offices. When an autopsy is requested, the decision about toxicological testing is at the discretion of the medical examiner responsible for the autopsy. The cases that were the primary focus of the CSL are a subset of the 77% of coroner-certified deaths for which an autopsy was not requested, since those are the cases for which the testing decision rests with the coroner's office. Specifically, the 2012 CSL targeted those deaths for which a cause could not be clearly established. The CTU evaluation focused broadly on all coroner-certified deaths for which an autopsy was not requested (N=36,848). This group of cases was identified as coroner-certified, non-autopsy deaths (CC-NA) within this report.

Table 3. Autopsy utilization in coroner-certified deaths in Kentucky (2010-2014)

	Autopsy requested		Autopsy not requested		Total deaths	
Year	N	%	N	%	N	%
2010	2,182	23.6	7,059	76.4	9,241	100.0
2011	2,178	23.3	7,179	76.7	9,357	100.0
2012	2,164	21.8	7,763	78.2	9,927	100.0
2013	2,142	22.8	7,270	77.2	9,412	100.0
2014	2,264	23.0	7,577	77.0	9,841	100.0
Total	10,930	22.9	36,848	77.1	47,778	100.0

Utilization of toxicological testing by coroner offices in Kentucky

Invoice records show that toxicological tests were performed by Axis Forensic Toxicology, formerly AIT Laboratories, between January 2010 and June 2015 for 8,351 Kentucky decedents. The annual test count increased from 1,332 tests in 2010 to 1,677 in 2014 (Table 4). The detailed approach to linking toxicological testing records with death records is described in Appendix A. The initial matching pass identified 6,990 total matches, of which 6,750 (96.5%) had no disagreements on any matching variables, and 240 (3.5%) had at least one disagreement. After quality assurance was conducted and further data cleaning was performed, a second linkage was conducted on unlinked toxicology and death records. An additional 259 candidate matches were identified by this process, of which 42 were judged upon review to be incorrect matches. This added another 217 matches for a total of 7,184 successfully matched toxicology records. As in indicator of the completeness of record linkage, we linked 95% all test records with a service date between 2010 and 2014 with a death that occurred between 2010 and 2014 (Table 5). The percentage of test records linked in 2013 and 2014 increased slightly over the percentages for 2010 through 2012. Following linkage of the death and testing data sets, we selected all CC-NA deaths (N=36,848) for inclusion in the CTU evaluation.

Table 4. Toxicological tests requested by coroners' offices[a] (2010-2014)

Year	Number of CC-NA deaths	Test records[a] (N)	Test records linked (N)	Test records linked (%)
2010	7,059	1,332	1,239	93%
2011	7,179	1,428	1,340	94%
2012	7,763	1,564	1,473	94%
2013	7,270	1,566	1,494	95%
2014	7,577	1,677	1,610	96%
Total	36,848	7,567	7,156b	95%

[a] By date of service, i.e. date test was processed

[b] N=28 toxicology records that linked with a death record from 2014 had a service date in 2015

Individual- and county-level influences on CTU

CTU in CC-NA deaths increased steadily from 16.6% in 2010 to 20.4% in 2014 (Table 5). This represents a statistically significant trend in CTU ($p<0.0001$). CTU varied significantly by age group (highest among decedents ages 18 to 34), gender (higher among males), race (lowest among blacks) and ethnicity (higher among Hispanics). CTU was slightly higher among coroners than among deputies. CTU was extremely low in large metro areas, a category including the counties that fall within the KIPDA and Northern Kentucky ADDs: Jefferson, Boone, Bracken, Bullitt, Campbell, Gallatin, Grant, Henry, Kenton, Oldham, Pendleton, Shelby, Spencer, and Trimble (Figure 3). (Table 6). These regions have high autopsy utilization by coroners, presumably due to their proximity to regional ME offices. If this is true, there may be low potential for improvement in CTU in these counties, post-CSL.

Table 5. Coroner toxicology use by decedent and county characteristics, coroner certified, non-autopsied deaths (2010-2014)

Characteristic	Number	Number tested	Percent tested	Statistic[a] (p value)
Year of death				-6.2 (<0.0001)
2010	7,059	1,170	16.6	
2011	7,179	1,307	18.2	
2012	7,763	1,452	18.7	
2013	7,270	1,417	19.5	
2014	7,577	1,548	20.4	
Decedent age (in years)				6,845 (<0.0001)
<18	333	80	24.0	
18-34	2,005	1,183	59.0	
35-54	7,928	3,228	40.7	
55-74	15,395	2,121	13.8	
75+	11,187	282	2.5	
Decedent sex				202 (<0.0001)
Male	22,909	4,802	21.0	
Female	13,937	2,091	15.0	
Decedent race				72 (<0.0001)
White	34,566	6,605	19.1	
Black	2,027	236	11.6	
Other	77	19	24.7	
Decedent ethnicity				3.7 (0.05)
Hispanic	186	45	24.2	
Nonhispanic	36,638	6,847	18.7	
County urban classification[b]				1,301 (<0.0001)
Large metro	6,271	186	3.0	
Small metro	8,451	2,088	24.7	
Micropolitan	8,949	1,775	19.8	
Non-core	13,174	2,845	21.6	
Certifier				15.8 (<0.0001)
Coroner	18,859	3,677	19.5	
Deputy coroner	17,989	3,217	17.9	

[a] Large metro: Jefferson-Oldham-Trimble-Bullitt-Spencer-Shelby-Henry; Boone-Campbell-Kenton-Pendleton-Grant-Bracken-Gallatin. Small metro: Fayette-Scott-Woodford-Bourbon-Clark-Jessamine; Greenup-Boyd; Christian-Trigg; Warren-Edmonson-Allen-Butler; Hardin-Meade-Larue; Daviess-Henderson-McLean-Hancock. Micropolitan: Anderson, Ballard, Barren, Bath, Bell, Boyle, Calloway, Franklin, Fulton, Graves, Hopkins, Knox, Laurel, Lincoln, Livingston, McCracken, Madison, Mason, Menifee, Metcalfe, Montgomery, Nelson, Pulaski, Rockcastle, Taylor, Whitley. Non-core: Adair, Breathitt, Breckinridge, Caldwell, Carlisle, Carroll, Carter, Casey, Clay, Clinton, Crittenden, Cumberland, Elliott, Estill, Fleming, Floyd, Garrard, Grayson, Green, Harlan, Harrison, Hart, Hickman, Jackson, Johnson, Knott, Lawrence, Lee, Leslie, Letcher, Lewis, Logan, Lyon, McCreary, Magoffin, Marion, Marshall, Martin, Mercer, Monroe, Morgan, Muhlenberg, Nicholas, Ohio, Owen, Owsley, Perry, Pike, Powell, Robertson, Rowan, Russell, Simpson, Todd, Union, Washington, Wayne, Webster, Wolfe.

[b] For year of death, Z statistic for Cochran-Artmitage Trend Test; for other variables, Pearson Chi-Square.

Figure 3. Coroner toxicology use rate and number of coroner certified, non-autopsied deaths by county (2010-2014)

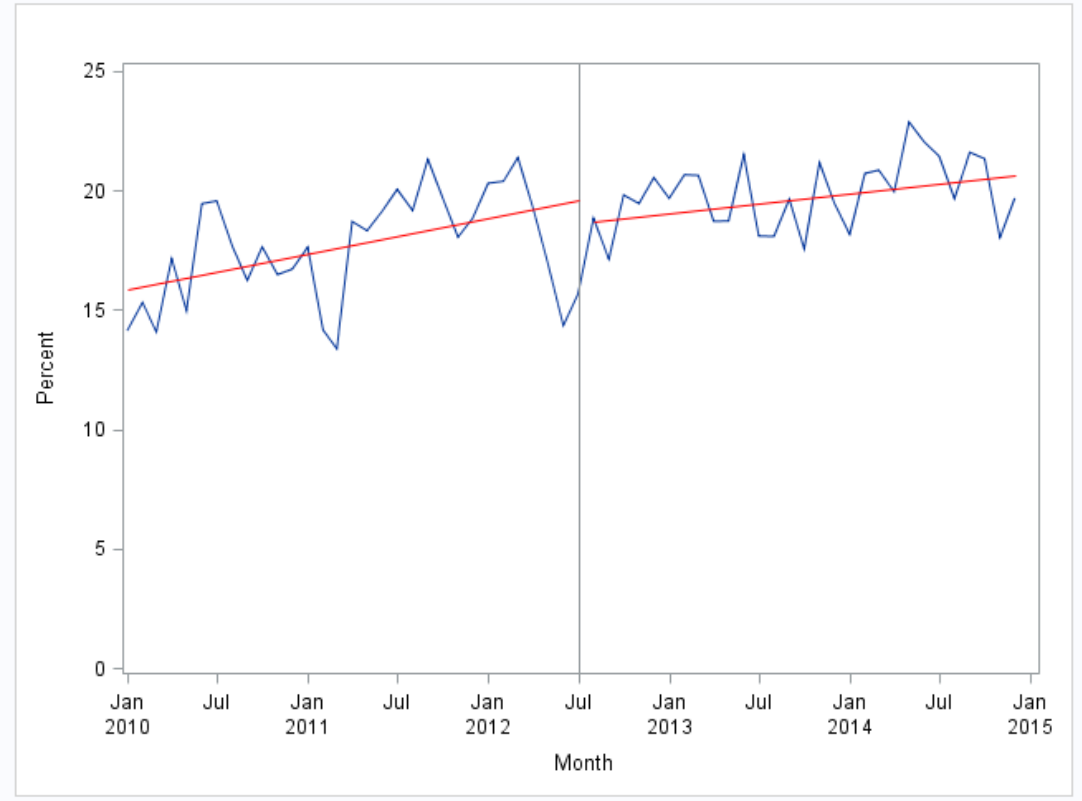
Table 6. Coroner toxicology use by Area Development District (2010-2014)

ADD	Number of deaths	Toxicology tests	Percent tested
Bluegrass	6,869	1,716	25.00%
KIPDA	5,297	146	2.80%
Cumberland Valley	3,565	753	21.10%
Barren River	2,898	516	17.80%
Big Sandy	2,807	592	21.10%
Purchase	2,333	502	21.50%
Kentucky River	2,208	501	22.70%
Lake Cumberland	2,171	541	24.90%
Pennyrile	1,919	288	15.00%
Lincoln Trail	1,584	230	14.50%
Green River	1,252	291	23.20%
FIVCO	1,211	408	33.70%
Northern KY	1,174	90	7.70%
Gateway	1,100	278	25.30%
Buffalo Trace	457	42	9.20%
Total	36,845	6,894	18.70%

Interrupted time series analysis

A statistically significant (p=0.002) increase in mean CTU occurred over the period from January 2010 and July 2012, prior to the CSL. This is indicated by the upward sloping, red line to the left of the CTL implementation reference line in Figure 4). However, there was no statistically significant change in mean statewide CTU immediately following implementation of the CSL (p=0.29). Although the slope of the red line for mean CTU in the post-CSL period appears to be slightly less than the slope of the red line for mean CTU in the pre-CSL period, the difference in slopes was not statistically significant (p=0.40). These results suggest that any effects that the CSL law might have had on CTU were local or regional, rather than statewide.

Figure 4. Interrupted time series analysis for mean coroner toxicology use before and after controlled substances testing law implementation



Local and regional change point analyses

To assess possible local and regional changes in CTU, a change point analysis was conducted. Instead of testing for a change at a specific point in time, change point analysis allows for the possibility of identifying multiple changes in the mean level of CTU over time.

County level

Most Kentucky counties had too few coroner-certified, non-autopsy deaths per month to enable a reliable change point analysis. We conducted monthly change point analyses for five counties with 15 or more coroner-certified, non-autopsy deaths per month from 2010 to 2014: Jefferson, Fayette, Warren, McCracken and Pike (Appendix B, Figure B-1).

In two of these five counties, there was an upward shift in mean CTU immediately following implementation of the CSL. In Fayette County, mean CTU increased by 32%, from 26% in July 2012 to 34.4% in August 2012. In Warren County, mean CTU increased by 48%, from 14.3% in Aug 2012 to 21.2% in Sept 2012.

In the three other high-CC-NA counties, there was no apparent shift in mean CTU with CSL implementation. In Pike County there was no evidence of any change over the evaluation period; CTU in Pike County appeared to fluctuate around a stable mean value of 26%. In McCracken County there was a 140% increase in CTU percentage from 18.9% in Nov 2011 to 45.4% in Dec 2011. However, this shift occurred 6 months prior to CSL implementation. One year later, in Dec 2012, mean CTU in McCracken County declined by 32% to 30.8%, where it remained for the duration of the evaluation period.

In Jefferson County, CTU was low throughout the evaluation period. Nevertheless, there was a significant 131% increase in CTU in Jefferson County approximately 15 months following the CSL, from 1.3% in Sept 2013 to 3.0% in Oct 2013. The relationship of this change to the CSL is unclear.

Area Development District level

Change point analyses at the level of area development district show results similar to the county-level analysis. A gradual, upward trend in unadjusted CTU was observed in FIVCO ADDs following CSL implementation (Appendix B, Figure B-2). Only in Kentucky River ADD was there a detectable shift in mean CTU immediately following CSL implementation: from 20.4% in June 2012 to 25.4% in July 2012. In four ADD's there was an upward shift in mean CTU between 7 and 14 months <u>after</u> the CSL. In six ADD's there was no detectable shift in mean CTU at any point during the evaluation period (Appendix B, Figure B-3).

<u>Summary</u>

There was a significant trend of increasing CTU statewide over the study period. There was no evidence of a widespread, immediate increase in CTU following implementation of the CSL, but localized increases occurring shortly after implementation were detected in Fayette and Warren Counties and in the Kentucky River ADD. There were also localized increases in several ADDs from 7 to 14 months later. These changes may not be solely attributable to CSL implementation but may represent the multiple intervention and policy efforts to increase CTU and SDR There was a steady increase in Warren County throughout the evaluation period,

from 7% to 31%.

Specificity of Drugs Mentioned on the Death Certificate

While the primary intent of the CSL was to increase the use of toxicology testing by coroners and medical examiners, its secondary purpose was to increase the listing of toxicology results on drug overdose death certificates. There were 6,267 coroner-certified drug overdose (CCDO) deaths from July 2010 through June 2016 (Table 7). SDR in those cases increased significantly (Cochran-Armitage trend test, X=-7.5, p<0.0001) from 69.2% in second half of 2010 to 80.6% in the first half of 2016. An autopsy was requested by the coroner in in 3,393 (54.1%) of CCDO deaths. SDR for both autopsy and non-autopsy CCDO deaths was 69% in 2010. By the end of 2012, SDR in autopsied cases increased to 77.3%, whereas in non-autopsied cases, SDR increased to 71.1%. In the first half of 2016, SDR in autopsy (80.7%) and non-autopsied (80.4%) cases was equivalent.

Table 7. Specificity of drugs on death certificates in all coroner-certified drug overdose deaths in Kentucky, by year and autopsy status (July 2010 – June 2016)

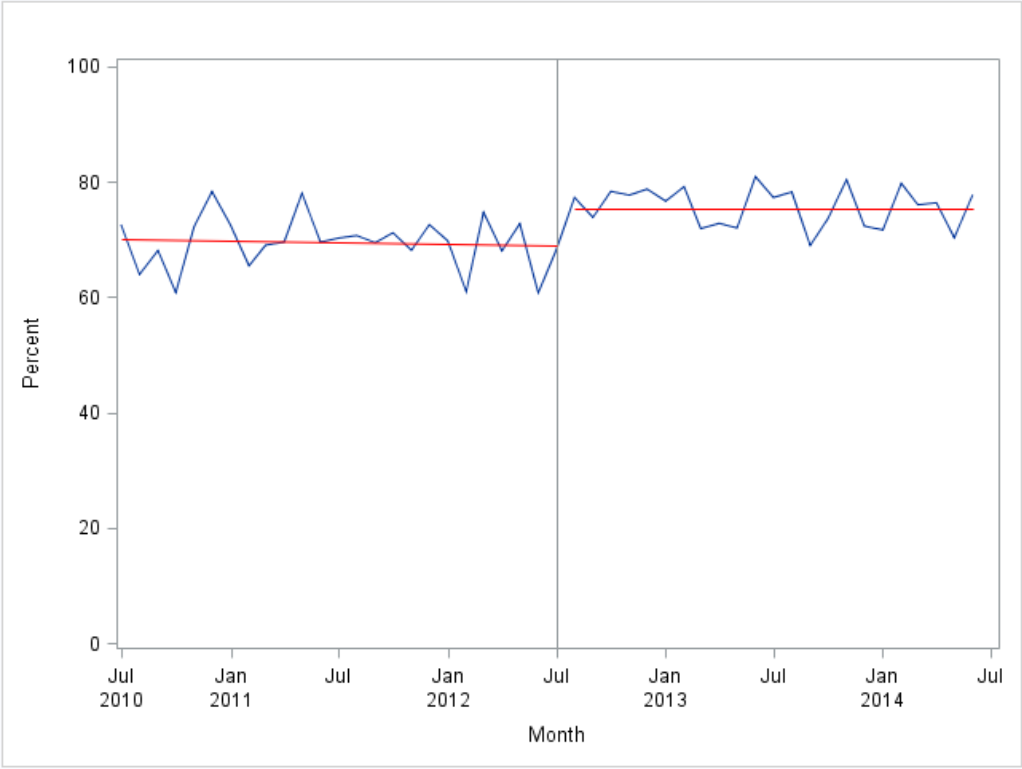
	All CCDO deaths			CCDO deaths not autopsied			CCDO deaths autopsied		
Year	Deaths (n)	Specific (n)	Specific (%)	Deaths (n)	Specific (n)	Specific (%)	Deaths (n)	Specific (n)	Specific (%)
2010[a]	448	310	69.2	199	138	69.4	249	172	69.1
2011	994	701	70.5	445	303	68.1	549	398	72.5
2012	1,011	722	71.1	444	284	64	567	438	77.3
2013	956	720	75.3	432	312	72.2	524	408	77.9
2014	1,028	806	78.4	472	353	74.8	556	453	81.5
2015	1,187	950	80	560	444	79.3	627	506	80.7
2016[b]	643	518	80.6	322	259	80.4	321	259	80.7
Total	6,267	4,727	75.4	2,874	2,093	72.8	3,393	2,634	77.6

[a] July through December
[b] January through June

Interrupted time series analysis

There was a statistically significant increase of 6.5 percentage points in the mean level of SDR immediately following CSL implementation CSL (p=0.01). However, in the two-year periods preceding (p=0.70) and following (p=0.79) CSL implementation, there was no statistically significant change in mean SDR (see red trend lines in Figure 5).

Figure 5. Interrupted time series analysis for statewide mean specificity of drugs before and after controlled substances testing law implementation



Geographic variation in autopsy utilization and SDR

SDR over the period from July 2010 to July 2016 varied greatly across the state (Figure 6). Jefferson County, which had the largest number of CCDO deaths during that period, had a relatively low rate of specific drugs mentioned on the death certificate.

Table 8 further explores the regional variation in autopsy utilization and SDR. Autopsy utilizations ranged from a low of 26.4% in Big Sandy ADD to 84.3% in KIPDA ADD, and there were clear geographic patterns. On the basis of autopsy utilization in CCDO deaths at the ADD level, four broad regions having similar levels of autopsy utilization can be defined. Figure 7 visualizes autopsy utilization by county in those four regions in relation to the location of Kentucky's regional ME offices. Region I (North) consists of Lincoln Trail, KIPDA, Northern Kentucky, Buffalo Trace and Gateway ADD's. Overall autopsy utilization in CCDO deaths in this region was 81%. Most of the counties in this region are close to one or more regional ME offices. Region II (Southeast) consists of FIVCO, Big Sandy, Kentucky River, Lake Cumberland and Cumberland Valley ADD's. Counties in this region do not have easy access to a regional ME office. Overall autopsy utilization in this region in CCDO deaths was 32%. Region III (Central) corresponds to Bluegrass ADD. Several of the counties in this region have easy access to the Central KY ME office in Franklin County.

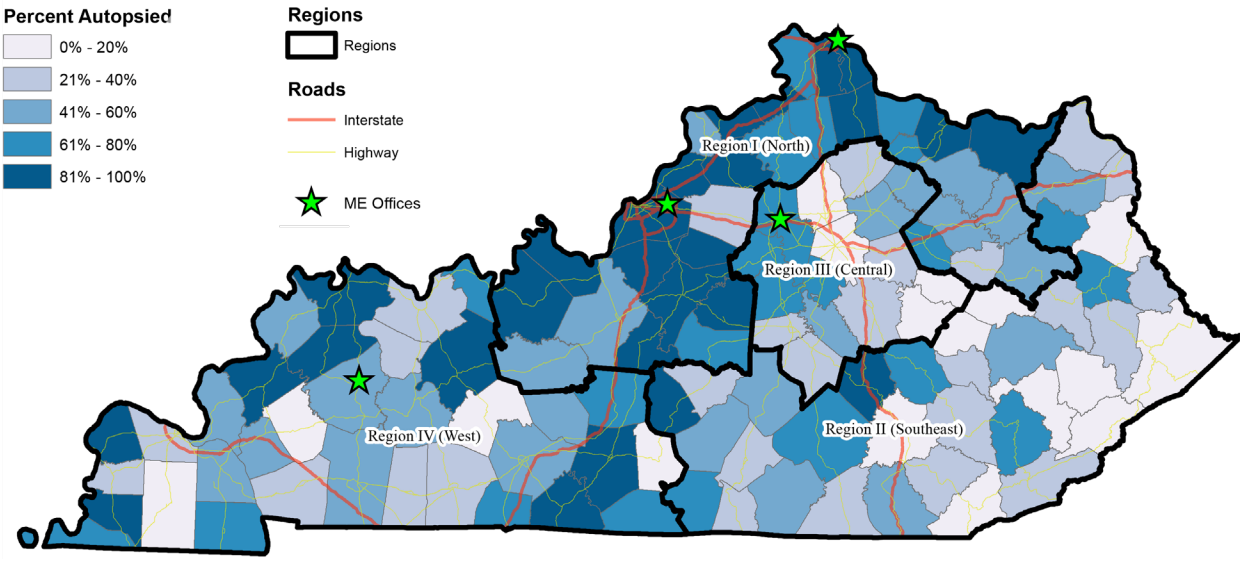
Figure 6. Specificity of drugs on death certificates in corner-certified drug overdose deaths in Kentucky by county, July 2010 – July 2016

Table 8. Observed specificity of drugs on death certificates by Area Development District, all coroner-certified drug overdose deaths in Kentucky (July 2010-June 2016)

ADD	All CCDO deaths			CCDO deaths autopsied			CCDO deaths not autopsied			% autopsied
	Deaths (N)	Specific (N)	Specific (%)	Deaths (N)	Specific (N)	Specific (%)	Deaths (N)	Specific (N)	Specific (%)	
Purchase	203	115	56.6	77	59	76.6	126	56	44.4	37.9
Pennyrile	168	94	55.9	81	60	74	87	34	39	48.2
Green River	184	128	69.5	100	76	76	84	52	61.9	54.3
Barren River	264	198	75	152	141	92.7	112	57	50.8	57.6
Lincoln Trail	204	172	84.3	147	136	92.5	57	36	63.1	72.1
KIPDA	1315	855	65	1108	747	67.4	207	108	52.1	84.3
Northern KY	961	760	79	788	634	80.4	173	126	72.8	82
Buffalo Trace	66	54	81.8	51	48	94.1	15	6	40	77.3
Gateway	97	81	83.5	58	50	86.2	39	31	79.4	59.8
FIVCO	198	181	91.4	59	52	88.1	139	129	92.8	29.8
Big Sandy	401	320	79.8	106	82	77.3	295	238	80.6	26.4
Kentucky River	277	160	57.7	77	53	68.8	200	107	53.5	27.8
Cumberland Valley	475	374	78.7	155	128	82.5	320	246	76.8	32.6
Lake Cumberland	261	192	73.5	112	93	83	149	99	66.4	42.9
Bluegrass	1193	1043	87.4	322	275	85.4	871	768	88.1	27
Statewide	6,267	4,727	75.4	3,393	2,634	77.6	2,874	2,093	72.8	54.1

Anderson, Mercer and Woodford counties autopsied more than two-thirds of CCDO deaths. Overall autopsy utilization for the region was 27%, similar to Region II. Fayette County, in particular, requested an autopsy in only 18% of CCDO deaths. Region IV (West) consists of Purchase, Pennyrile, Green River and Barren River ADD's. The area is served by the Western KY ME office in Hopkins County. Overall autopsy utilization was 50% - higher than in Regions II and III but lower than in Region I.

Figure 7. Regional differences in autopsy utilization (July 2010-June 2016)



Pre-post analysis of SDR by Medical Examiner involvement

The CSL became effective on July 15, 2012, denoted as CSL-1. The amendment that expanded the scope of the SCL mandate became effective on March 15, 2015, denoted as CSL-2. Therefore, the evaluation period from July 2010 through June 2016 can be divided into three periods: the pre-CSL-1 period from July 1, 2010 – July 14, 2012; the period post-CSL-1 and pre-CSL-2; and the period post-CSL-2. Table 9 presents SDR in each of these periods by the regions defined above. Results are stratified into SDR by coroner autopsy request status. Several observations can be made:

1. The most striking changes following initial CSL implementation (i.e. post-CSL-1) occurred in Region IV (Western KY). SDR increased from 28% to 59% (111% increase) when an autopsy was requested, and from 58% to 94% (62% increase) when an autopsy was not requested. Region IV had the lowest pre-implementation baseline SDR, meaning that it had the greatest room from improvement. Additionally, there was no further increase in SDR in this region after the amendment, i.e. post-CSL-2.
2. In regions II and III, in cases where an autopsy was not requested there was little change in SDR following initial implementation. These were areas where autopsy utilization in

CCDO deaths was low. In cases where an autopsy was requested in these regions, there were modest increases in SDR post-CSL-1. In both of these regions, the CSL amendment appeared to have a greater impact than the original law, for both autopsy and non-autopsy cases.

3. In region IV, where more than 80% of CCDO deaths were autopsied, there were modest increases in SDR following initial implementation for both autopsy and non-autopsy cases. Following amendment, there was another modest increase in SDR in non-autopsy cases, but a decrease in cases where an autopsy was requested.

These changes suggest associations between SDR and the original CSL and the amendment. To further elucidate the possible effects of the CSL on SDR we also performed (1) a time series change point analysis of SDR in Kentucky from July 2010 through June 2016, and (2) a time series comparison of SDR in Kentucky and four control states having similar death investigation systems, from January 2006 through December 2014.

Table 9. Specificity of drugs on death certificates in corner-certified drug overdose deaths in Kentucky by region[a], pre-post controlled substances testing law interval, and by medical examiner involvement, July 2010 – June 2016

Region[a]	Deaths (N)	Deaths (%)	SDR (%)		
			Pre CSL-1[b]	Post CSL-1 / Pre CSL-2[c]	Post CSL-2[d]
I (Northern)					
No autopsy	491	19	54	62	67
Autopsy	2,152	81	72	78	74
II (Southeastern)					
No autopsy	1,103	68	72	71	87
Autopsy	509	32	75	80	95
III (Central)					
No autopsy	871	73	86	88	90
Autopsy	322	27	78	83	98
IV (Western)					
No autopsy	409	50	28	59	57
Autopsy	410	50	58	94	93

[a] Region I includes Lincoln Trail, KIPDA, Northern Kentucky, Buffalo Trace and Gateway ADD's; Region II includes FIVCO, Big Sandy, Kentucky River, Cumberland River and Lake Cumberland ADD's; Region III includes Bluegrass ADD; Region IV includes Purchase, Pennyrile, Green River, and Barren River ADD's.

[b] July 1, 2010 – July 14, 2012; [c] July 15, 2010 – March 14, 2015; [d] March 15, 2015 – June 30, 2016

Change point analysis, July 2010 – June 2016

Figure 8 presents the shifts in statewide, seasonally-adjusted, mean SDR that were detected from the latter half of 2010 through the first half of 2016. Overall, mean SDR increased in the period between initial implementation and amendment of the CSL, by 16% (13.5 percentage points), before falling and then partially recovering after the amendment. The following shifts in mean SDR were detected:

- From 69.5% in July 2012 to 75.7% in August 2012
- From 75.7% in June 2014 to 83.0% in July 2014
- From 83.0% in June 2015 to 75.7% in July 2015
- From 75.7% in December 2015 to 80.3 in Jan 2016

In contrast with CTU, the shifts in mean SDR that occurred between July 2010 and June 2016 can be tracked to changes in specific regions of the state.

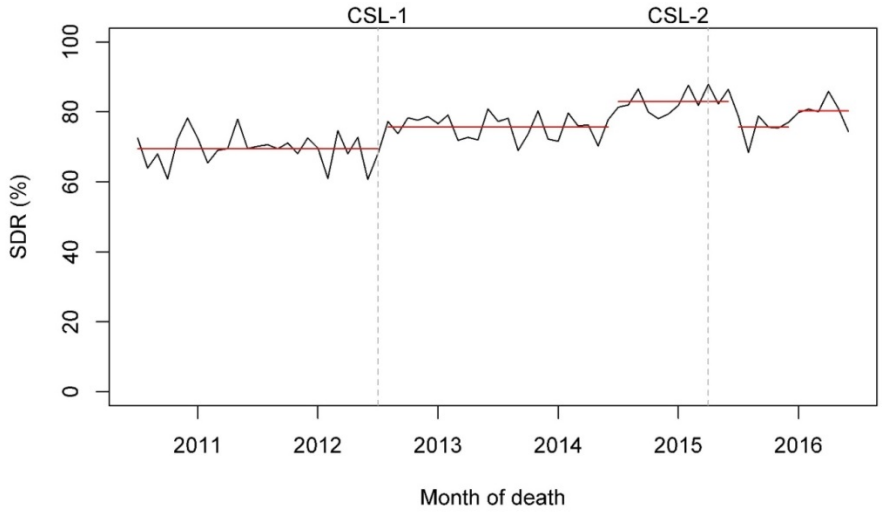
The first of these mean shifts coincides with the initial implementation of the CSL. Looking at Figure C-1 (Appendix C), we see that these shifts occurred primarily in the western part of the state (Region IV): Purchase, Pennyrile, Green River and Barren River ADD's. There were also upward shifts in KIPDA ADD, when SDR is examined separately for autopsy and non-autopsy cases. The second, later statewide shift was due to an increase early in 2014 in Bluegrass ADD and increases in the second half of 2014 in the southeastern part of the state (Region II): Kentucky River, Cumberland Valley, Lake Cumberland and Big Sandy ADD's.

The statewide drop in mean SDR that occurred between June and July of 2015 – 3 to 4 months after the effective date of the amended CSL – corresponds to declines in the northern and in western parts of the state, possibly due to medical examiner vacancies in those areas during that time period. The recovery in early 2016 corresponds to an increase in the western part of the state.

In the ADD's comprising the Northern region, where 63% of all CCDO autopsies were performed, mean SDR in autopsy cases was 71%. ***In the rest of the state combined, SDR in autopsy cases exceeded 95% by 2016***. In the ADD's comprising the Central and Southeast regions, where 69% of all CCDO deaths without ME involvement (no autopsy) occurred, SDR was approaching 90% in early 2016. In the Northern and Western regions of the state, which rely more heavily on autopsy for determining cause of death in drug overdose cases, SDR in cases without ME involvement deaths was in the low- to mid-60's.

Thus, increases in SDR during the evaluation period varied greatly depending on geographic region and ME involvement.

Figure 8. Estimated shifts in monthly mean statewide specificity of drugs[a] on death certificates for all coroner-certified drug overdose deaths in Kentucky (July 2010-June 2016)



Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, monthly SDR. Mean shifts were detected from 69.5% in July 2012 to 75.7% in August 2012; from 75.7% in June 2014 to 83.0% in July 2014; from 83.0% in June 2015 to 75.7% in July 2015; and from 75.7% in December 2015 to 80.3 in Jan 2016.

Comparison with control states

Alabama, Arkansas, Indiana, and South Carolina were selected as comparison states because their death investigation systems resemble Kentucky's mixed coroner/ medical examiner system. Kentucky is a coroner state with a centralized medical examiner system that serves only in an advisory capacity. All four states are coroner states. Alabama coroners are supported by a mostly centralized medical examiner's office. Alabama's population size is similar to that of Kentucky. Arkansas, also a centralized medical examiner system, supplements coroner investigations. While Indiana does not have a centralized medical examiner system, each coroner contracts with forensic pathologists to provided autopsy services. Kentucky's Chief Medical Examiner's Office is contracted to perform autopsies for many of the counties in southern Indiana. Lastly, South Carolina has a similar population size served by elected coroners and a decentralized medical examiner system.

In none of the four comparison states was a change point detected during the period in which Kentucky's CSL was implemented (Appendix C, Figure C-2). This finding argues against any national, secular effect as a cause of the 9% increase (69.8% to 76.1%; 6.3 percentage points) statewide in mean SDR observed in Kentucky at the time the CSL was implemented.

Interestingly, in South Carolina, mean SDR jumped from 59% to 94.4% at the beginning of 2014 (See Appendix C, Figure C-2). This was a result of a direct appeal to coroners by the state health department to submit information on specific drugs involved in drug overdose deaths.

The state health department amended the death certificates with that information.

CSL Impact on Coroner Perception of Toxicology Testing

Law Impact

In response to the survey question "Have drug overdose investigations changed since 2012 [when CSL was enacted]?" 63% of coroners responded affirmatively. Drug overdose investigations changed both in volume of investigations (72.4%) and in higher caseloads (58.6%). In additional, 89.7 % of respondents indicated that drug overdose investigations changed through increased use of toxicology testing.

Toxicology Result Use by Coroners

Where the cause of death was not known, 60.9% of respondents used toxicology results to determine the underlying causes and contributing cause(s) of death. In deaths where the suspected cause was a drug overdose, 80.4% answered that they always relied on toxicology results to determine the cause of death. Another 19.6% indicated that they often relied on the toxicology results to determine cause of death when they suspected that the cause of death was a drug overdose.

Among all respondents, 50% responded that they always listed the drugs involved in an overdose death on the death certificate. Among the respondents who received special training, 46.2% reported that they always list the specific drugs on the death certificate. Another 20.5% reported that they often list specific drugs on the death certificate. Of the 80.4% that reported relying on toxicology results to determine the cause of death in drug overdose deaths, 54.1% responded that they always listed specific drugs on the death certificate.

Most (84.8%) of respondents reported receiving specific training on investigating suspected drug overdoses. Of these respondents, 73.1% reported that they always use the toxicology results to complete the death certificate. However, only 46.2% of the trained respondents reported that they always list the specific drugs involved in the overdose deaths on the death certificate.

Facilitators and Barriers to Toxicology Results Use by Coroners

In identifying facilitators of toxicology result use, the respondents replied that training always (56.5%) or often (21.7%) helped. Two other facilitators were directly tied to the State Medical Examiner Office. The sample collection kits provided by the State Medical Examiner Office at no cost to the coroners were identified as always helpful by 65.2% of respondents and as often helpful by another 21.7%. The availability of a medical examiner to assist with the interpretation of toxicology testing results was always helpful to 32.2% of respondents and

often helpful to another 24.4%.

The length of time for toxicology testing results to be completed was never (45.6%) or rarely (30.4%) a barrier to the use of toxicology results by respondents. The difficulty in determining the specific drugs involved in causing poly-substance overdose deaths was identified as sometimes (34.8%) or often (8.7%) a barrier to the listing of specific drugs on death certificates. The inability to list all of the drugs involved in a death on the electronic death certificate was an identified barrier by 30.4% as 'sometimes', and another 23.9% as 'often'. The fact that the listing of drugs on death certificates is not required was identified as always a barrier by only 10.9% of respondents and often a barrier by 6.5%.

Reporting of Prescriber Information

Almost all (93.5%) coroners reported collecting prescriber information for prescription drugs present at the scene of a drug overdose. This information was used by 72.1% of respondents to determine the underlying cause of death. Over half (55.8%) informed law enforcement personnel of the prescriber information. Another one-quarter (25.6%) used the information to inform prevention efforts. Only 16.3% of respondents used the data to inform prescribers' licensure boards.

Limitations of the CSL Evaluation

Evaluation of the impact of CSL on CTU may be underestimated for a number of reasons. First, coroner investigation reports are not mandated although they could assist in identifying drug overdose death cases where coroners were unable able to establish causes of death without CTU. Second, there were already a number of educational and death investigation process quality improvement efforts in place prior to CSL implementation, that could have impacted both CTU and SDR listings on death certificates. Unfortunately, it was impossible to assess and evaluate which coroners were exposed to each of these initiatives, at which time, and with what level of intensity. As a proxy, the qualitative coroner survey developed and administered to provide additional self-report data could have been biased and/or incomplete.

Cost Analysis

Kentucky's economic burden of drug overdose deaths is substantial: using the standard statistical life valuation of $9 million, the total cost was $9.171 billion in 2013 and $9.693 billion in 2014. A much more conservative estimate of an adjusted $1.2 million, based solely on anticipated earnings, still yields costs of $1.228 billion in 2013 and $1.292 billion in 2014 and $1.556 billion in 2015. Thus, any intervention that reduces this escalating burden has the potential for significant cost impact over time. However, before an intervention can be characterized as cost-effective, it must be found to be effective, that is, it must have achieved its intended goal. The CSL results above show that the CSL has been effective in increasing CTU and SDR.

Association with increased testing and reporting

The proportion of coroner-certified deaths for which toxicological testing was performed has increased in every year since 2010 (Table 5). Importantly, the proportion of death certificates listing specific drugs increased by 11.4 percentage points between 2011 and 2016 (Table 7).

As noted earlier in this report, interrupted time series analysis demonstrated a statistically significant increase of 6.5 percentage points in the mean level of SDR immediately following CSL implementation CSL (p=0.01). Much of this increase in SDR occurred in Western Kentucky. Change point analyses demonstrated locally significant increases in the mean level of CTU, immediately following CSL implementation, in Fayette County, Warren County, and Kentucky River ADD, and within one year of CSL implementation in Gateway, FIVCO and Barren River (excluding Warren County) ADDs.

Costs

Despite the increase in testing, aggregate costs of toxicology tests ordered by coroners and MEs combined actually dropped by 3.2% in the post-enactment period (comparing 2011 and 2015 data) because the per-test costs for commonly used tests declined (Table 10). For example, the "drugs of abuse" panel cost was reduced from $125 to $120, then to $107.50, and the "comprehensive" panel decreased from $165 to $160. The aggregate costs of tests ordered by coroners rose by 11% over the same period, while costs for ME toxicology tests fell by 12%.

Table 10: Coroner and Medical Examiner Overdose-Related Toxicology Test Costs by Fiscal Year

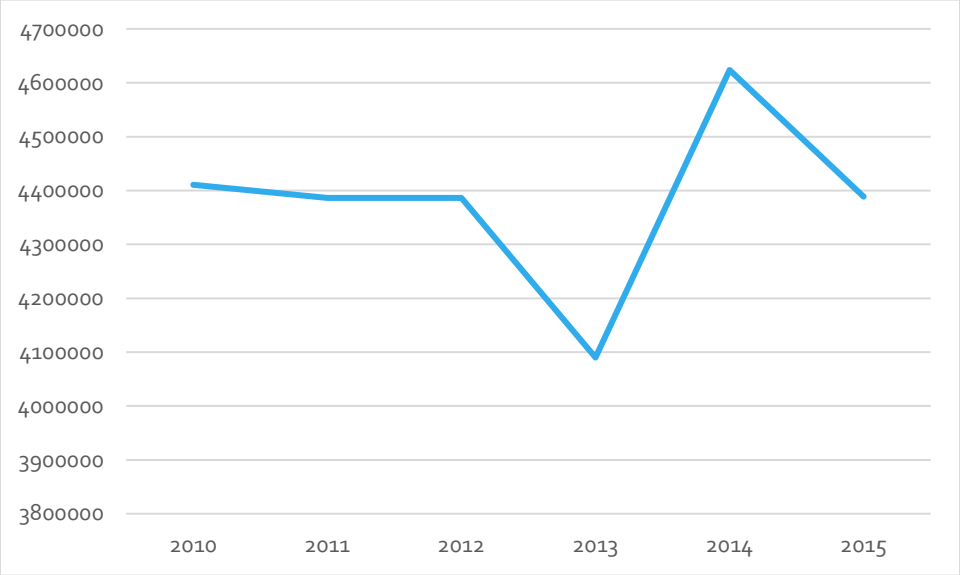
Fiscal Year	Coroner Test Costs	% Change	Med Examiner Test Costs	% Change	Total Test Costs	% Change
2010	$ 152,179		$ 292,152		$ 444,331	
2011	$ 170,146	11.81%	$ 273,300	-6.45%	$ 443,446	-0.20%
2012	$ 198,429	16.62%	$ 276,667	1.23%	$ 475,096	7.14%
2013	$ 168,339	-15.16%	$ 289,081	4.49%	$ 457,420	-3.72%
2014	$ 177,224	5.28%	$ 283,249	-2.02%	$ 460,473	0.67%
2015	$ 188,837	6.55%	$ 240,602	-15.06%	$ 429,439	-6.74%

Autopsies are obviously much more expensive than even the most comprehensive toxicological testing, ranging from approximately $2500-4000, depending on costs associated with transporting the remains and forensic testing. Other relevant costs include the transportation of remains to state medical examiner offices for autopsy, additional time associated with the increase in investigations, and increased coroner education through the state's Office of Criminal Justice Training (OCJT). A survey of the state's coroners found that the mean cost of transporting remains was approximately $200, and that most investigations took between one and four hours. These costs appear to have been absorbed within the coroners' annual budgets. Inquiries with OCJT found that the additional training was

performed by salaried or contracted staff within their normal scope of work; the costs were not broken out in the OCJT budget in a manner that supported analysis of any incremental financial outlay.

At the level of the medical examiner offices, comparison of expenses for the period 2010-2015 showed a substantial increase in 2014 (Fig. 9). ME staff identified this change as related to a temporary increase in the cost of forensic pathologist staffing because of unfilled regular positions.

Figure 9. State Medical Examiner Program Budget (in dollars)



Dissemination of surveillance findings

One mechanism by which mandated decedent testing could affect overdose rates is dissemination of surveillance findings. The nature and volume of surveillance dissemination has increased since enactment of the CS testing law, thanks in part to the increase in drug specification on death certificates. Historical issues with alignment of the ME reports and those of the state Office of Drug Control Policy (ODCP) appear to have been resolved in tandem with improvements in testing and reporting. However, current data do not support or refute the hypothesis that mandated testing would reduce overdose rates through dissemination of test findings.

Assessing magnitude of potential benefit

Based on the conservative valuation of each life saved at $1.262 million, exclusive of the broad range of social costs incurred, if the decedent testing mandate were found to have saved even a single life per year, the social benefit would be about triple the total cost of decedent testing

statewide ($426,225), when both metrics are adjusted to 2010 dollar values. This cost-benefit ratio of 3:1 would make decedent testing a highly valuable addition to states' multifaceted initiatives to address the ravages of opioid abuse and overdose. The host of intervening variables between increased decedent controlled substance testing and avoided drug overdose deaths impedes our ability to identify causation for the purpose of cost-benefit analysis. The addition of data for upcoming years may support a more definitive assessment.

References

[1] Ky Constitution Section 100.

[2] KRS 72.025.

[3] LaMantia, SL. Office of the Medical Examiner 2015 Calendar Year Annual Report. 2015. http://justice.ky.gov/Documents/Medical%20Examiners/2015%20FINAL%20Annual%20Report%20OME%20new.pdf

[1] Robinson LA, Hammitt JK. Valuing reductions in fatal illness risks: implications of recent research. Health Econ. 2015; DOI 10.1002/hec.3214.

[1] Grosse SD, Krueger KV, Mvundura M. Economic productivity by age and sex, 2007 estimates for the United States. Med Care 2009; 47 (7 Suppl 1):S94-103.

Auger IE, Lawrence CE (1989). "Algorithms for the Optimal Identification of Segment Neighborhoods." Bulletin of Mathematical Biology, 51(1), 39–54.

Bai J, Perron P (1998). "Estimating and Testing Linear Models with Multiple Structural Changes." Econometrica, 66(1), 47–78.

Killick R, Eckley I, Haynes K (2014). changepoint: An R Package for Changepoint Analysis. R package version 1.1.5, URL http://CRAN.R-project.org/package=changepoint.

Killick R, Eckley IA, Jonathan P, Ewans K (2010). "Detection of Changes in the Characteristics of Oceanographic Time-Series using Statistical Change Point Analysis." Ocean Engineering, 37(13), 1120–1126.

Scott AJ, Knott M (1974). "A Cluster Analysis Method for Grouping Means in the Analysis of Variance." Biometrics, 30(3), 507–512.

Sen A, Srivastava MS (1975). "On Tests for Detecting Change in Mean." The Annals of Statistics, 3(1), 98–108.

Appendices

Appendix A – Methodology

METHODS

Data sources

Kentucky death certificate files

The Kentucky Department for Public Health, Vital Statistics Branch (VSB), is responsible for the collection of death certificate records in Kentucky under KRS 213. We obtained death certificate files from the VSB for deaths occurring in Kentucky between 2010 and 2014. Data elements of interest for this evaluation include the certifier, underlying cause of death (for identifying overdose deaths), supplemental causes of death (for assessing specificity of reported drugs involved in overdose deaths), and those required for linking death records with toxicological testing records.

Coroner-requested toxicological testing records

From 2010 through 2015, all toxicological testing in Kentucky – whether requested by a coroner or a medical examiner (ME) – was conducted by American Institute of Toxicology (AIT) Laboratories. We were unable to obtain toxicological testing records access from AIT. Instead we obtained, from the Kentucky Cabinet for Justice and Public Safety, invoice records of toxicology tests ordered by coroners and ME's in Kentucky from 2010 through the June 2015. (For the purpose of this evaluation, testing by coroners was of primary interest). Invoice records were provided in the form of hard copy lists and electronic PDF files. PDF files were converted automatically into Excel spreadsheets and cleaned. Data elements from the hard copy lists were entered manually into Excel.

NCHS Multiple Cause of Death Files

Multiple Cause of Death (MCOD) files from the National Center for Health Statistics (NCHS) were accessed from CDC WONDER in order to compare Kentucky's historical trend for drug specificity with selected states having similar death investigations systems. NCHS receives death certificate files from all U.S. states annually through the National Vital Statistics System.

Record linkage

To determine whether toxicological testing was ordered for each death occurring in Kentucky from 2010 to 2014, we linked the death certificate and toxicology files using probabilistic record linkage (PRL) (Newcombe 1957; Fellegi and Sunter 1969; Clark 2004). PRL was used because errors (e.g. misspelling of names) and omissions on matching variables were expected, and because in general death date and service date were not expected to be equal. We matched on decedent name, county of death, and date of death vs. service date (i.e. the date the test was run by AIT). Only the first three characters of first and last name were used

for matching. Names on both data sources – but particularly on the toxicology file – required considerable preprocessing to prepare for linkage. Date of death and date of service were considered to be in agreement if date of service was within 30 days after the date of death. Candidate pairs of matched records were classified as correct or incorrect matches by generating multiple draws from the set of all candidate matched pairs, and selecting the draw with the maximum likelihood score (NTSA 2015). This process is less biased than classifying matches as correct based solely on having a match probability score above a threshold value. Extensive quality assurance was conducted on the record linkage process, including a second matching pass. Results are described below. PRL was implemented using LinkSolv version 9.0 (Strategic Matching Inc., Morrisonville NY).

Denominators

Coroner-certified deaths

The 2012 CSL was intended to increase utilization of toxicological testing by coroners in cases for which a cause of death could not be clearly determined (the 2015 amendment expanded the testing requirement to include all cases requiring a post-mortem examination under KRS 72.025). It is not possible to ascertain from the death certificate whether a cause of death could be clearly determined by the coroner upon initial investigation.

Outcome measures

Toxicology and autopsy utilization

We defined coroner toxicology utilization (CTU) as the proportion of coroner-certified, non-autopsy deaths for which a toxicology test was conducted by AIT. Autopsy cases were excluded because in such cases the testing decision rests with the ME, not the coroner.

We defined coroner autopsy utilization (CAU) as the proportion of coroner-certified deaths for which an autopsy was performed.

Specificity of drugs mentioned on death certificate

We defined specificity of drugs contributing to death (SDR) as the proportion of coroner-certified drug overdose deaths for which at least one specific ICD-10 drug code (T36-T50.8) was listed among the underlying and supplemental causes of death on the death certificate.

In exploratory data analysis, we noticed a large increase in SDR in mid-2010 (see Figure A-1, Appendix). We believe this increase to be an artifact of changes in the death certificate data collection process that occurred in 2010, which resulted in more complete capture of supplemental ICD-10 cause of death codes. Those supplemental codes are used to identify specific drugs, as mentioned above. Because of this, we believe SDR for January 2010 through June 2010 is artificially low, and we started the evaluation of SDR with July 2010.

Statistical analysis

To test for differences in CTU and SDR by age, gender and other categorical variables, we used the Pearson chi-square test. To test for statewide trends in annual rates of CTU and SDR we used the Cochrane Armitage test for trend. Hypothesis tests were run using SAS 9.4; significance level was 0.05.

To identify specific changes in mean CTU and SDR over time we used both interrupted time series and change point analyses (Scott and Knott 1974; Auger and Lawrence 1989; Bai and Perron 1998; Killick et al. 2012a). Change point analysis is capable of identifying the location of multiple shifts in the mean level of a time series. Interrupted time series (ITS) is an alternative approach to testing for changes in both level and trajectory of a time series at pre-specified time points, such as a policy intervention like Kentucky's CSL. Based on exploratory data analysis, it was apparent that both the number and timing of changes in the trajectories of CTU and SDR varied considerably across geographic areas (counties, ADD's), making both approaches appropriate for different aspects of this evaluation.

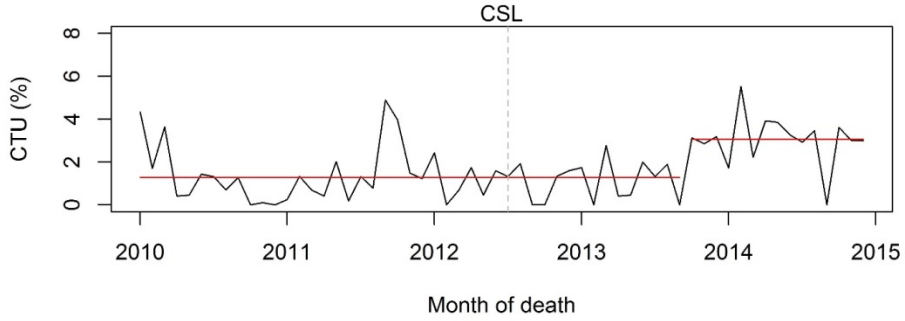
For all change point analyses, the actual monthly or quarterly values of CTU and SDR were seasonally adjusted using classic additive time series decomposition (SAS 9.4, PROC TIMESERIES). This process removes consistent periodic fluctuations from the series, to eliminate them as a possible explanation of any shifts in mean CTU that may be detected. In general, neither CTU nor SDR showed strong seasonality.

We used the R package *changepoint* (Killick and Eckley 2014) to carry out the change point analyses for CTU and SDR. The cpt.mean() function was used to identify, via binary segmentation , a set of change points for mean CTU and SDR that minimizes within-interval differences, while penalizing overfitting to the observed data. The CUSUM test statistic was used in order to avoid the assumption that CTU and SDR are normally distributed. The value of the overfitting parameter for each change point analysis was determined by manual inspection.

Appendix B – Supplemental figures for Coroner Toxicology Use analysis

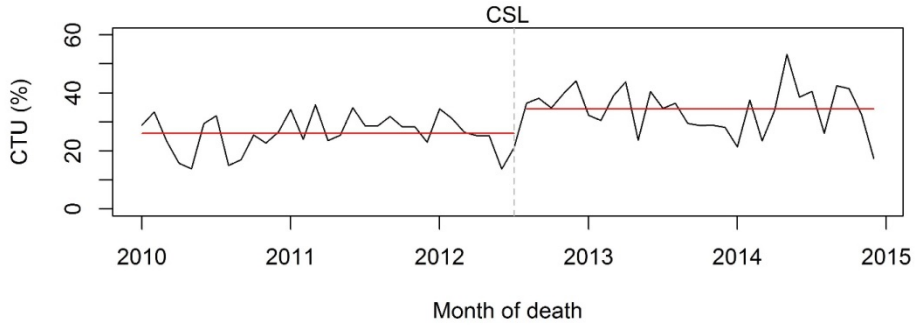
Figure B-1. Estimated mean coroner toxicology use for corner certified, non-autopsied deaths by county, 2010-2014
(Red lines indicate estimated means; black curves indicate seasonally-adjusted CTU)

A: Jefferson County



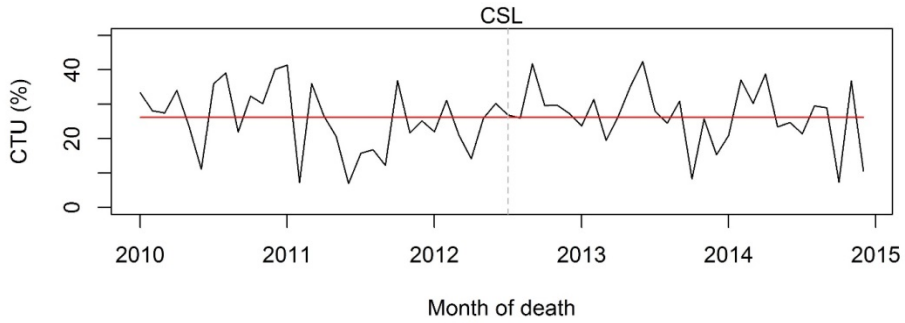
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 1.3% in Sept 2013 to 3.0% in Oct 2013.

B: Fayette County



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 26.0% in July 2012 to 34.4% in Aug 2012.

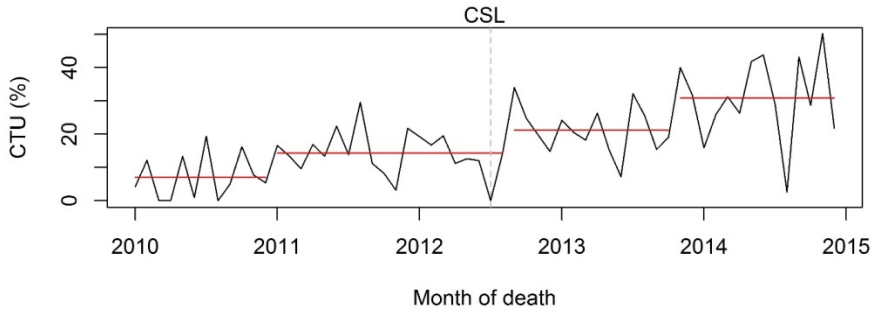
C: Pike County



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.

[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 26.2% over the evaluation period.

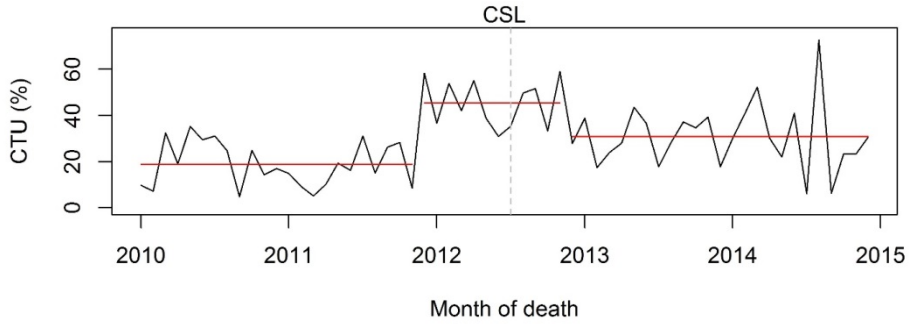
D: Warren County



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.

[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. Mean shifts were detected from 7.0% in Dec 2010 to 14.3% in Jan 2011; from 14.3% in Aug 2012 to 21.2% in Sept 2012; and from 21.2% in Oct 2013 to 30.9% in Nov 2013.

E: McCracken County



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.

[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. Mean shifts were detected from 18.9% in Nov 2011 to 45.4% in Dec 2011; and from 45.4% in Nov 2012 to 30.8% in Dec 2012.

Figure B-2. Observed coroner toxicology use by Area Development District (not adjusted for seasonality)

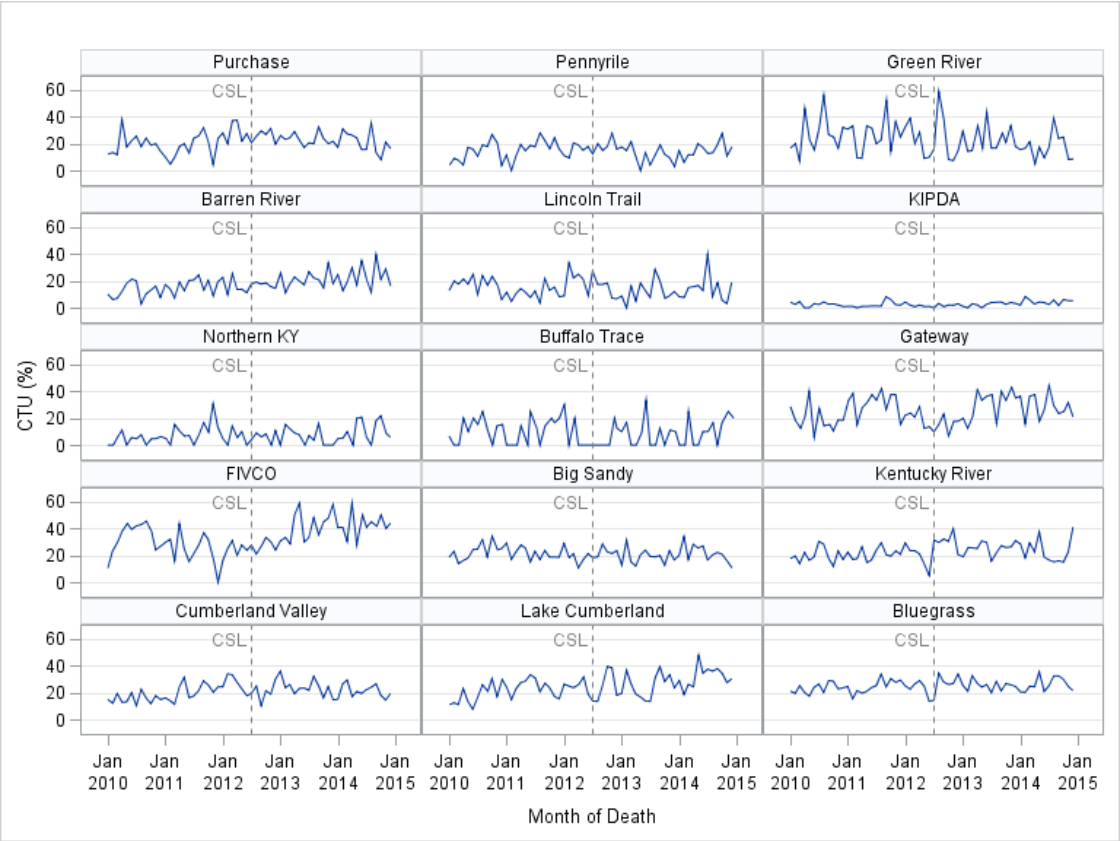
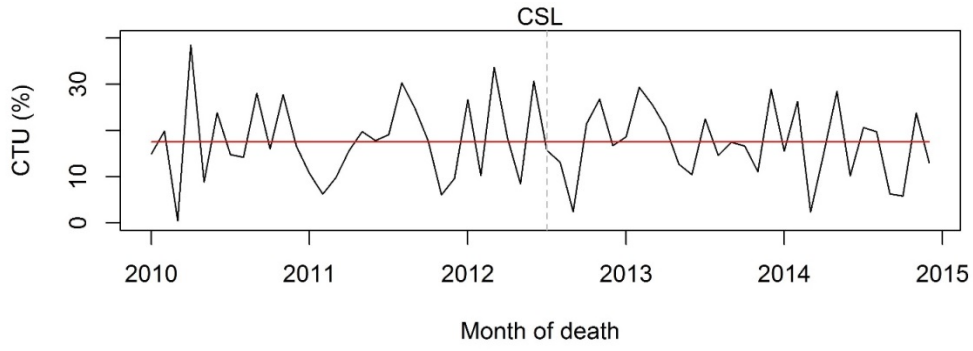


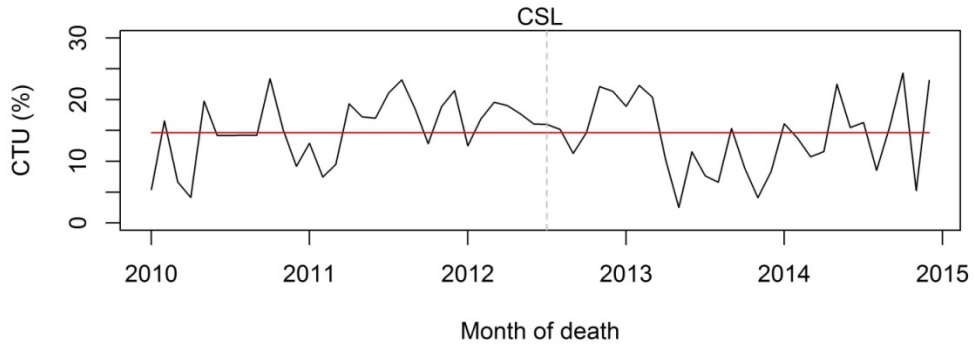
Figure B-3. Estimated mean coroner toxicology use for coroner-certified, non-autopsy deaths by Area Development District, 2010-2014
(Red lines indicate estimated means; black curves indicate seasonally-adjusted coroner toxicology use)

A: Purchase Area Development District, minus McCracken County



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 17.5% over the evaluation period.

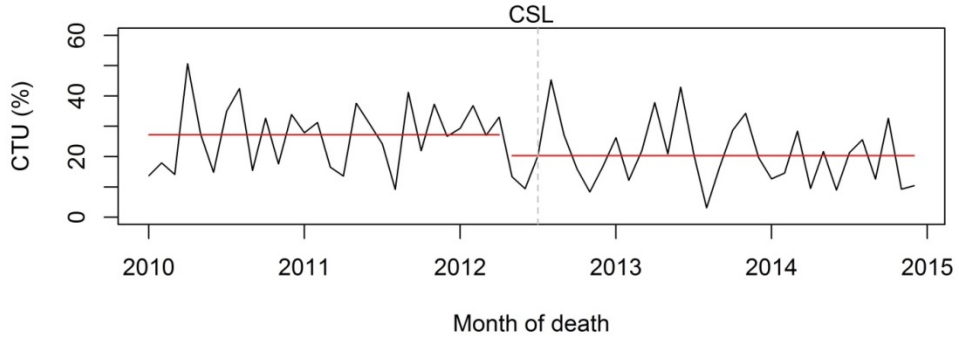
B: Pennyrile Area Development District



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.

[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 14.6% over the evaluation period.

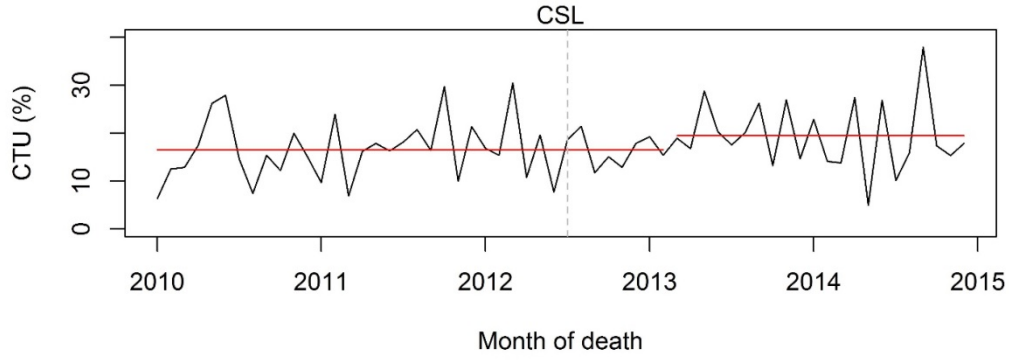
C: Green River Area Development District



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.

[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 27.2% in Apr 2012 to 20.7% in May 2012.

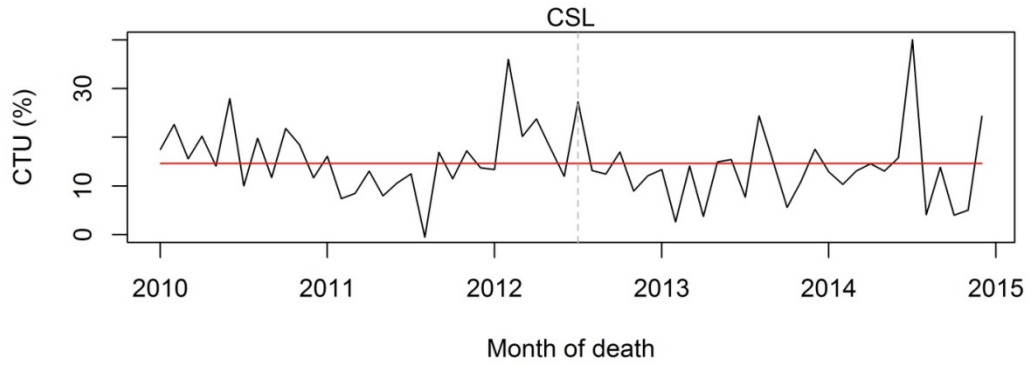
D: Barren River Area Development District, minus Warren County



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.

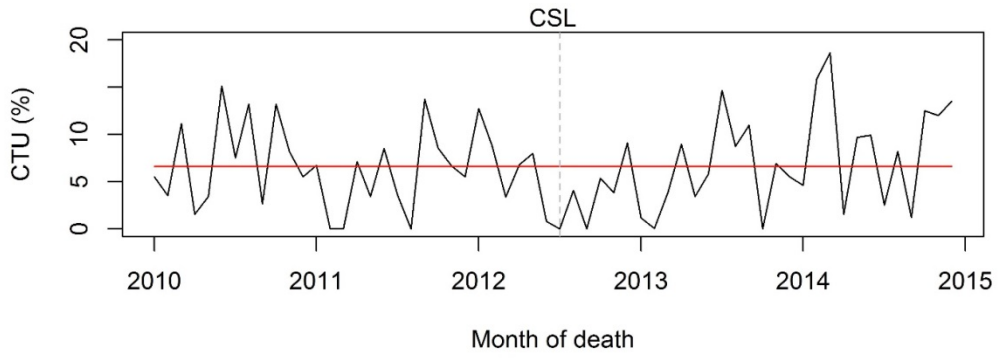
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 16.5% in Feb 2013 to 19.5% in Mar 2013.

E: Lincoln Trail Area Development District



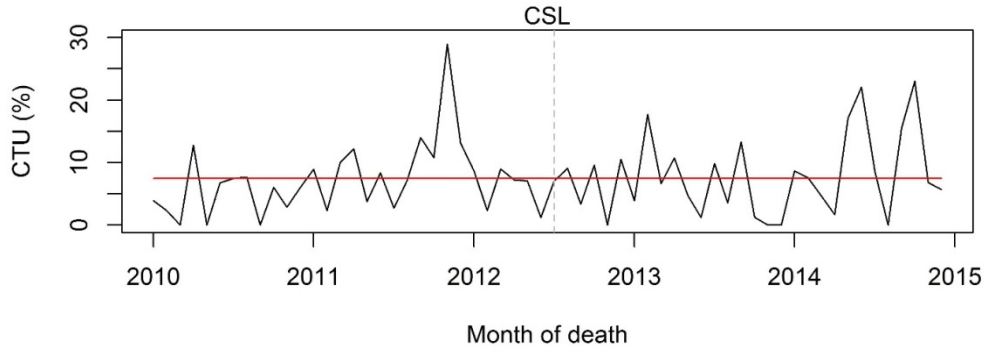
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 14.6% over the evaluation period.

F: KIPDA Area Development District, minus Jefferson County



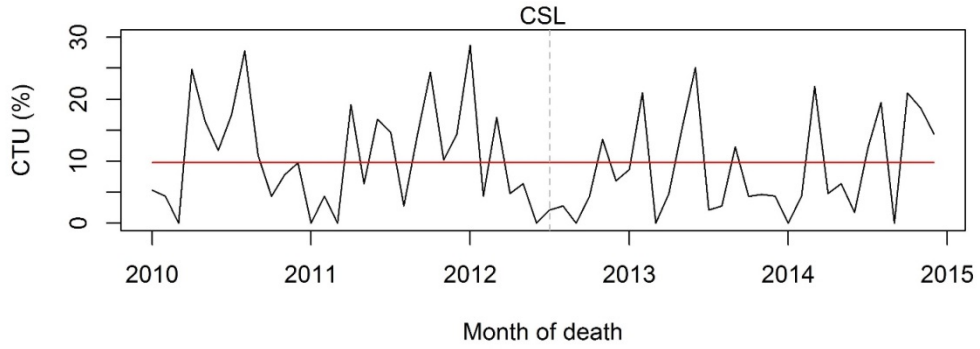
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 6.6% over the evaluation period.

G: Northern Kentucky Area Development District



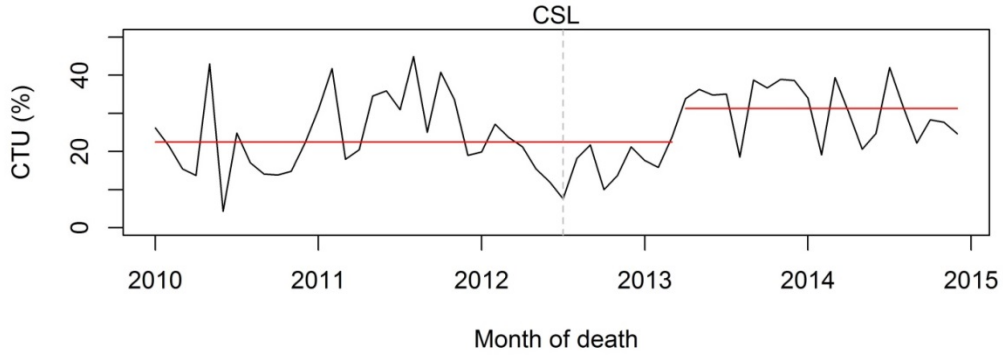
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 7.5% over the evaluation period.

H: Buffalo Trace Area Development District



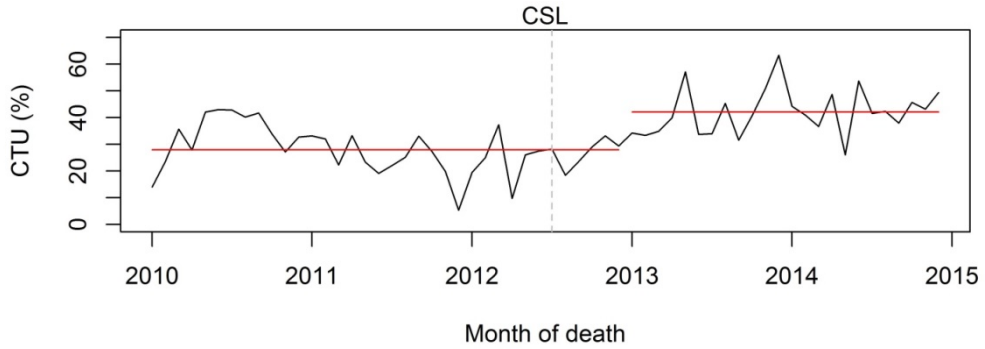
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 9.8% over the evaluation period.

I: Gateway Area Development District



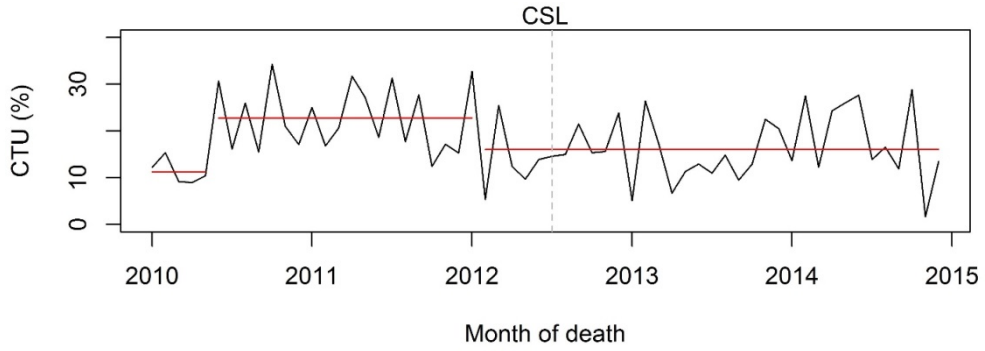
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 22.5% in March 2013 to 31.2% in April 2013.

J: FIVCO Area Development District



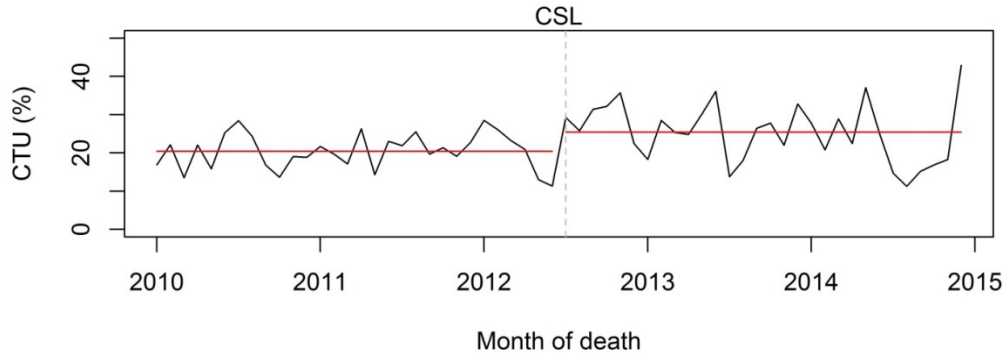
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 28% in Dec 2012 to 42% in Jan 2013.

K: Big Sandy Area Development District, minus Pike County



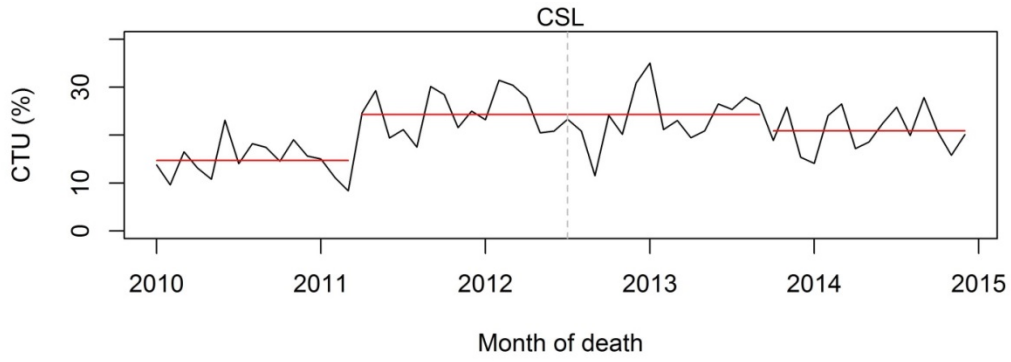
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. Mean shifts were detected from 11.2% in May 2010 to 22.7% in June 2010; and from 22.7% in Jan 2012 to 16.0% in Feb 2012.

L: Kentucky River Area Development District



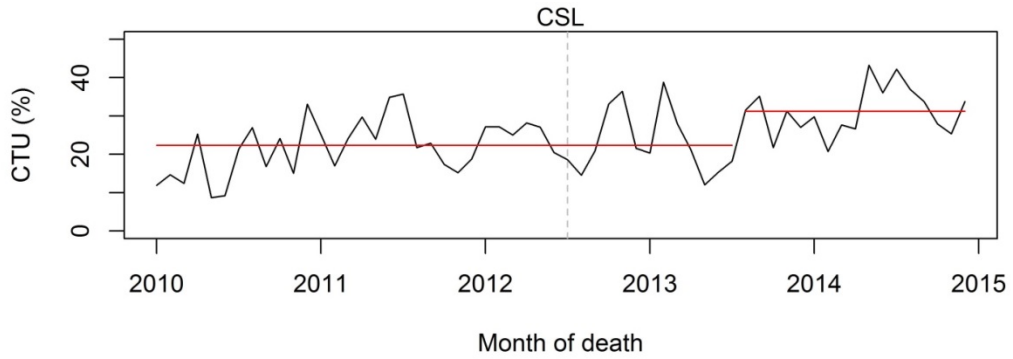
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 20.4% in June 2012 to 25.4% in July 2012.

M: Cumberland Valley Area Development District



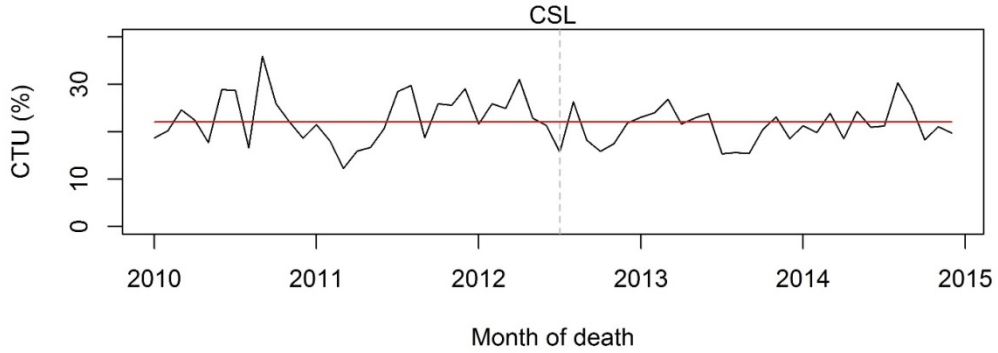
Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. Mean shifts were detected from 14.7% in March 2011 to 24.3% in April 2011; and from 24.3% in Sept 2013 to 20.9% in October 2013.

N: Lake Cumberland Area Development District



Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. A mean shift was detected from 22.3% in July 2013 to 31.2% in Aug 2013.

O: Bluegrass Area Development District, minus Fayette County

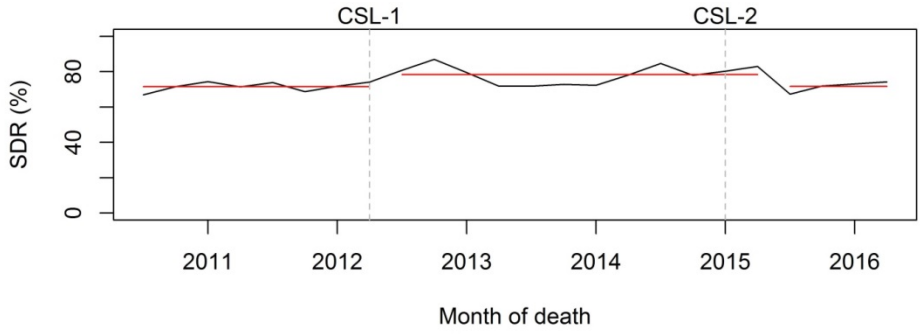


Data source: KY Death Certificates. CSL indicates the effective date for the CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly CTU. No mean shift was detected; estimated mean was 22% over the evaluation period.

Appendix C – Supplemental Figures for Specificity of Drugs analysis

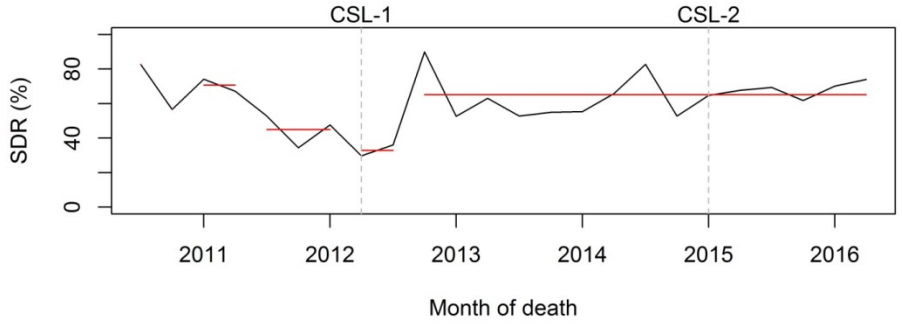
Figure C-1. Estimated shifts in quarterly mean specificity of drugs on drug overdose death certificates[a] by region (July 2010 – June 2016)

A. Region I[b] (North) – Coroner-certified drug overdose deaths with autopsy



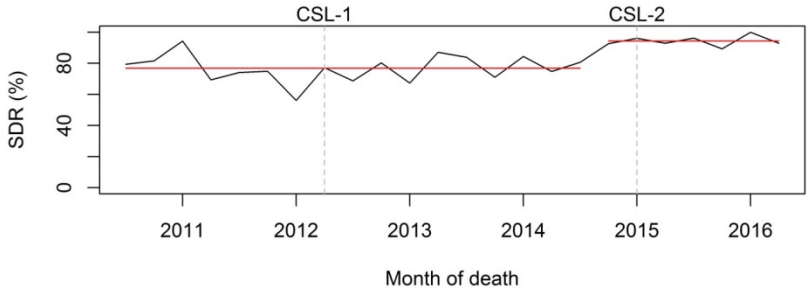
Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment
[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. Mean shifts were detected from 71.6% in 2012 Q2 to 78.3% in 2012 Q3; and from 78.3% in 2015 Q2 to 71.6% in 2015 Q3.
[b] Region I includes Lincoln Trail, KIPDA, Northern Kentucky, Buffalo Trace and Gateway ADD's

B. Region I[b] (North) – Coroner-certified drug overdose deaths with no autopsy



Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment
[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. Mean shifts were detected from 70.6% in 2011 Q2 to 44.9% in 2011 Q3; from 44.9% in 2012 Q1 to 32.9% in 2012 Q2; and from 32.9% in 2012 Q3 to 65.1% in 2012 Q4.
[b] Region I includes Lincoln Trail, KIPDA, Northern Kentucky, Buffalo Trace and Gateway ADD's

C. Region II[b] (Southeast) – Coroner-certified drug overdose deaths with autopsy

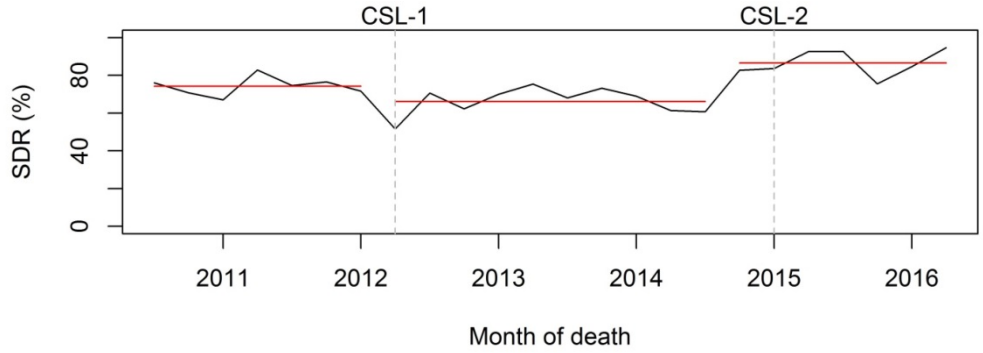


Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. A mean shift was detected from 76.8% in 2014 Q3 to 94.3% in 2014 Q4.

[b] Region II includes FIVCO, Big Sandy, Kentucky River, Cumberland River and Lake Cumberland ADD's

D. Region II[b] (Southeast) – Coroner-certified drug overdose deaths with no autopsy

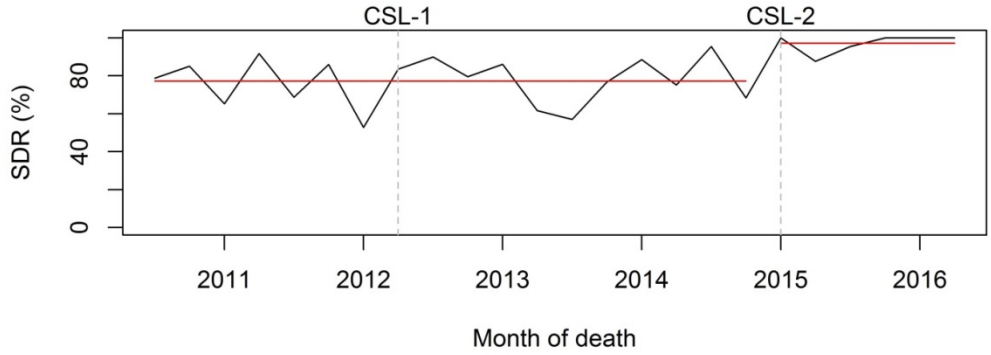


Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. Mean shifts were detected from 74.2% in 2012 Q1 to 66.2% in 2012 Q2; and from 66.2% in 2014 Q3 to 86.6% in 2014 Q4.

[b] Region II includes FIVCO, Big Sandy, Kentucky River, Cumberland River and Lake Cumberland ADD's

E. Region III[b] (Central) – Coroner-certified drug overdose deaths with autopsy

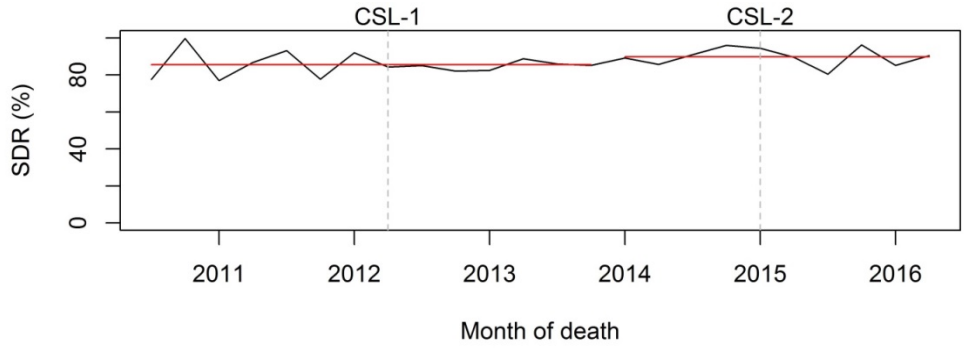


Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. A mean shift was detected from 77.2% in 2014 Q4 to 97.2% in 2015 Q1.

[b] Region III includes Bluegrass ADD

F. Region III[b] (Central) – Coroner-certified drug overdose deaths with no autopsy

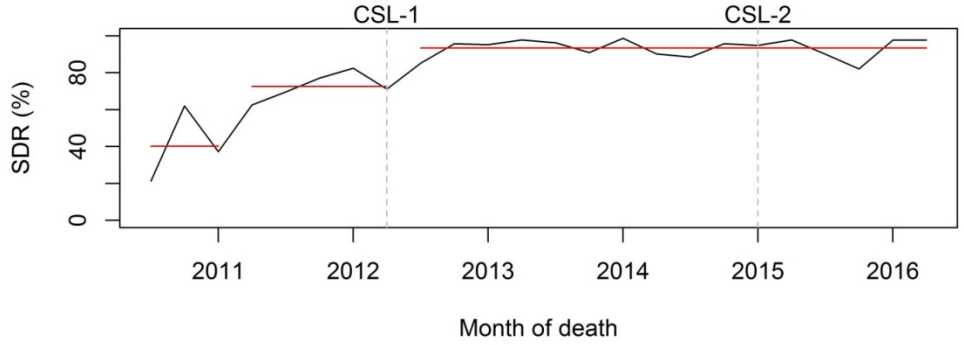


Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. A mean shift was detected from 85.5% in 2013 Q4 to 89.8% in 2014 Q1.

[b] Region III includes Bluegrass ADD

G. Region IV[b] (West) – Coroner-certified drug overdose deaths with autopsy

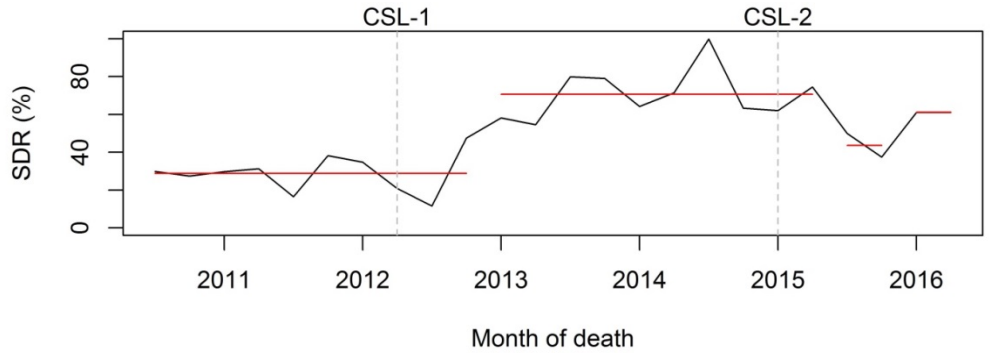


Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. Mean shifts were detected from 40.2% in 2011 Q1 to 72.6% in 2011 Q2; and from 72.6% in 2012 Q2 to 93.4% in 2012 Q3.

[b] Region IV includes Purchase, Pennyrile, Green River and Barren River ADD's

H. Region IV[b] (West) – Coroner-certified drug overdose deaths with no autopsy



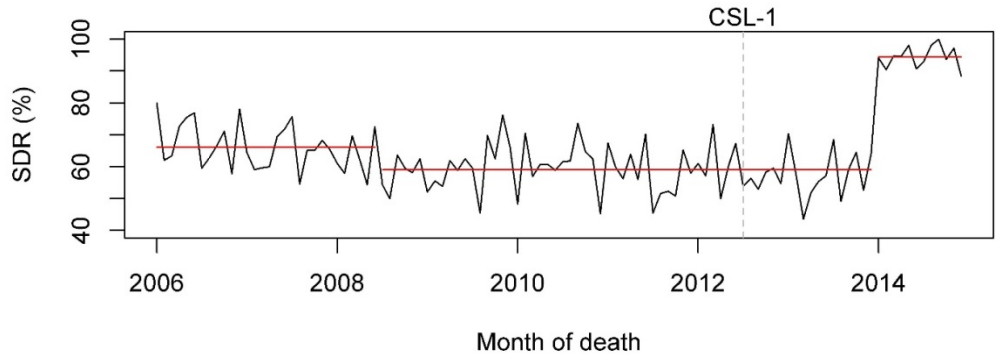
Data source: KY Death Certificates. CSL-1 and CSL-2 represent effective dates for CSL law and amendment

[a] Estimated by change point analysis using seasonally-adjusted, quarterly SDR. Mean shifts were detected from 28.8% in 2012 Q4 to 70.7% in 2013 Q1; from 70.7% in 2015 Q2 to 43.7% in 2015 Q3; and from 43.7% in 2015 Q4 to 61.1% in 2016 Q1.

[b] Region IV includes Purchase, Pennyrile, Green River and Barren River ADD's

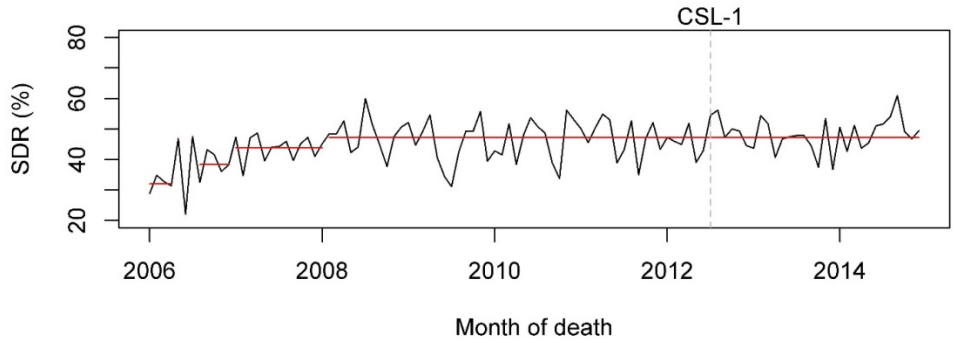
Figure C-2. Estimated shifts in monthly mean specificity of drugs on death certificates[a] for all drug overdose deaths[b] by state (2006-2014)

A. South Carolina



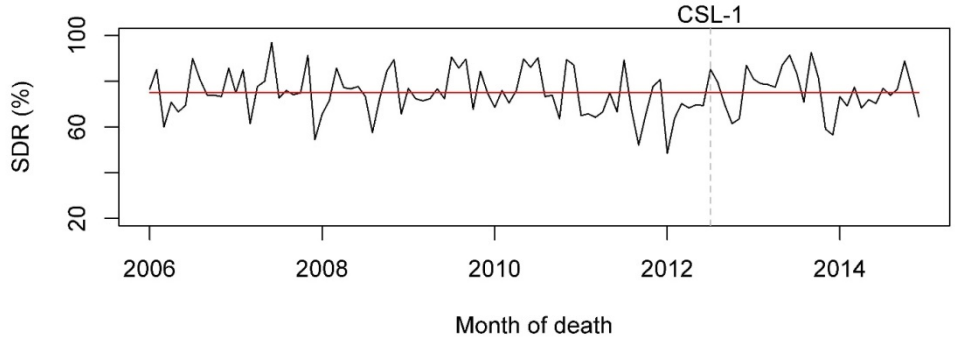
Data source: CDC WONDER, Multiple Cause of Death Files. CSL-1 represents the effective date for Kentucky's CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly SDR. Mean shifts were detected from 66.1% in June 2008 to 59.0% in July 2008; and from 59.0% in Dec 2013 to 94.4% in Jan 2014.
[b] CDC WONDER does not allow querying by death certifier, so state comparisons based on Multiple Cause of Death Files could not be restricted to coroner-certified drug overdose deaths.

B. Indiana



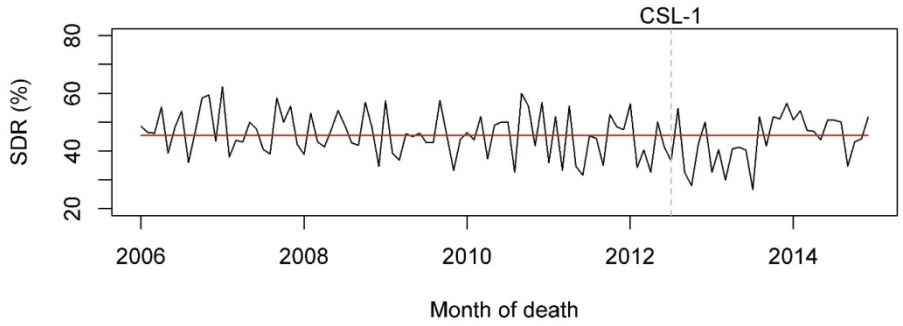
Data source: CDC WONDER, Multiple Cause of Death Files. CSL-1 represents the effective date for Kentucky's CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly SDR. Mean shifts were detected from 38.4% in Dec 2006 to 43.9% in Jan 2007; and from 43.9% in Jan 2008 to 47.2% in Feb 2008.
[b] CDC WONDER does not allow querying by death certifier, so state comparisons based on Multiple Cause of Death Files could not be restricted to coroner-certified drug overdose deaths.

C. Arkansas



Data source: CDC WONDER, Multiple Cause of Death Files. CSL-1 represents the effective date for Kentucky's CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly SDR. No mean shift was detected; mean SDR was estimated to be 75.0% over the evaluation period.
[b] CDC WONDER does not allow querying by death certifier, so state comparisons based on Multiple Cause of Death Files could not be restricted to coroner-certified drug overdose deaths.

D. Alabama



Data source: CDC WONDER, Multiple Cause of Death Files. CSL-1 represents the effective date for Kentucky's CSL law.
[a] Estimated by change point analysis using seasonally-adjusted, monthly SDR. No mean shift was detected; mean SDR was estimated to be 45.4% over the evaluation period.
[b] CDC WONDER does not allow querying by death certifier, so state comparisons based on Multiple Cause of Death Files could not be restricted to coroner-certified drug overdose deaths.

[i] Robinson LA, Hammitt JK. Valuing reductions in fatal illness risks: implications of recent research. Health Econ. 2015; DOI 10.1002/hec.3214.

[ii] Grosse SD, Krueger KV, Mvundura M. Economic productivity by age and sex, 2007 estimates for the United States. Med Care 2009; 47 (7 Suppl 1):S94-103.