

Scott, Robert L. (DHHS)

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 4:54 PM
To: Scott, Robert L. (DCH); Peeler, Nancy (DCH)
Cc: LyonCallo, Sarah (DCH); McKane, Patricia (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx
Attachments: City of Flint EBLL May 2011-Apr 2015_Final.pdf

Hello Nancy and Bob,

It turns out that adding in the additional two years of data did not change the results of the analysis: there does appear to be a higher proportion of EBLL last summer than usual. I wrote up my methods and results in the attached brief, just in case anyone asks for specifics.

Have a good night!
 Cristin

From: Scott, Robert L. (DCH)
Sent: Tuesday, July 28, 2015 10:15 AM
To: Larder, Cristin (DCH); Peeler, Nancy (DCH); McKane, Patricia (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

Cristin,

I can safely say I don't understand it without some explanation.

However, late yesterday Nancy and I decided to take a look two years farther back to see how they fit with the recent years. Please see attached, which I just finished this morning. Sorry I didn't have this for you yesterday before you did the analysis. Would this new information change the analysis?

Thanks,
 Bob

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 10:07 AM
To: Peeler, Nancy (DCH); McKane, Patricia (DCH)
Cc: Scott, Robert L. (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

Nancy and Bob,

Is the control chart clear enough, do you think? I could whip up a fact sheet with a description of what it shows, if you think it would help make it more digestible for our audience.

Cristin

From: Larder, Cristin (DCH)
Sent: Tuesday, July 28, 2015 9:25 AM
To: Peeler, Nancy (DCH); McKane, Patricia (DCH)

Cc: Scott, Robert L. (DCH)
Subject: RE: Flint Testing and EBLLs.xlsx

Hi Nancy,

I made a p-chart, which Shewhart's version of a control chart for proportions, for the data you sent. Basically, I used the monthly data from 2013-14 to create upper and lower control limits, then plotted the 2014-15 data in a run chart. It shows that the three months in question are the only ones that lie outside the control limit: in fact, they are the only points that lie well above the mean at all. This doesn't say anything about causality, but it does warrant further investigation.

There are several next steps we can employ if the folks upstairs ask us to look deeper into the data. Also, I'm not sure if you talked at all with the Environmental Health folks, but their toxicologists could probably help give us some context to the issue.

Cristin

From: Peeler, Nancy (DCH)
Sent: Monday, July 27, 2015 3:37 PM
To: McKane, Patricia (DCH)
Cc: Larder, Cristin (DCH); Scott, Robert L. (DCH)
Subject: Re: Flint Testing and EBLLs.xlsx

Thanks, Patti. I'm looking forward to hearing about your CollN meeting, I'm sure you will be bringing great information back.

Sent from my iPhone

On Jul 27, 2015, at 3:11 PM, "McKane, Patricia (DCH)" <McKaneP@michigan.gov> wrote:

Thanks Nancy.
 I was in a session on Shewart charts for QI. I think this might be a good approach for the needs assessment. We can talk more. Hopefully the slides will be available, because I can't type that much with my thumbs

Sent from my iPhone

On Jul 27, 2015, at 1:14 PM, Peeler, Nancy (DCH) <PeelerN@michigan.gov> wrote:

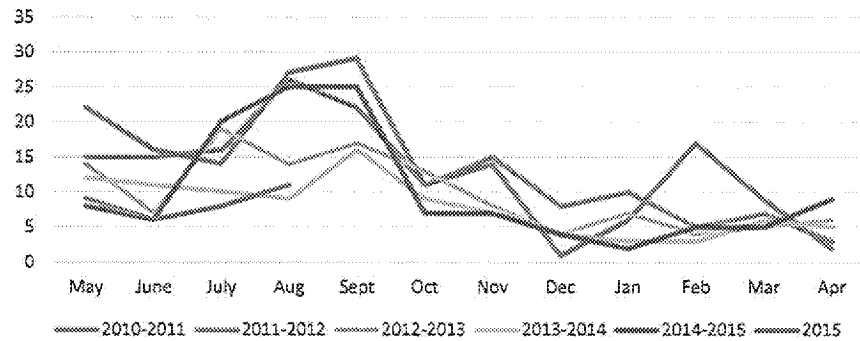
Hi Cristin and Patti –

This is the CLPPP data for Flint that I had mentioned to you last week. Cristin, can you quickly run any tests to see if the difference in the first graph is statistically significant? Bob is at his desk today, best to connect with him if you have questions about the data. We are hoping to send this up today, so we appreciate anything you can do to get us a response this afternoon, if at all possible. Many thanks!

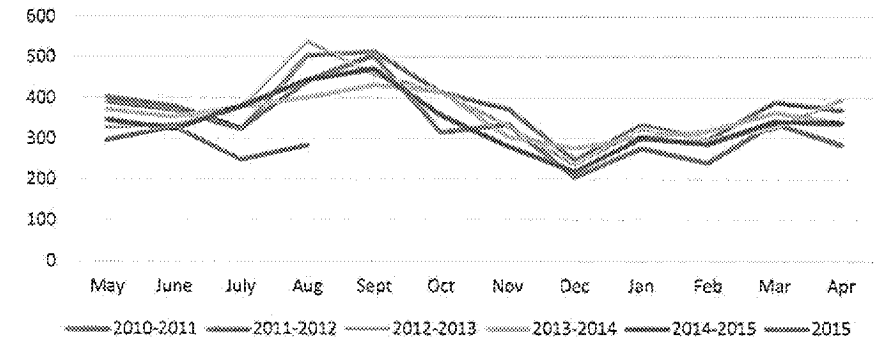
Nancy

<Flint Testing and EBLLs.xlsx>

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels*



City of Flint, Children less than 16 years of age
Tested for Lead Poisoning

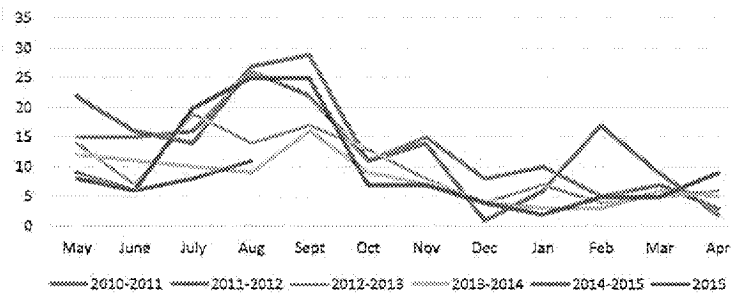


*Children whose address is listed as "Flint"--may not conform exactly to Flint city limits
 Less than 16 years of age at time of test
 Includes only first-time blood lead levels ≥ 5 ug/dL
 Includes sample type of venous, capillary or unknown

September 23, 2015

Source: MDHHS Data Warehouse, Lead Specimen table

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels*

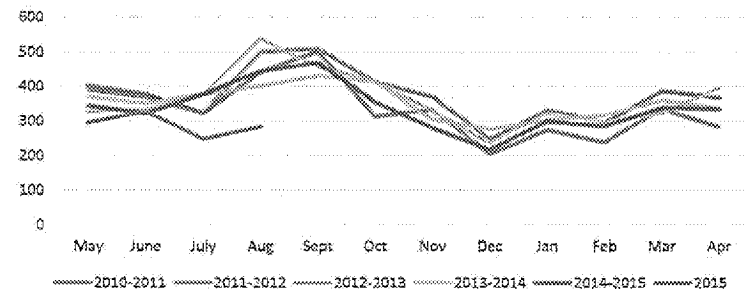


*Children whose address is listed as "Flint"--may not conform exactly to Flint city limits
Less than 16 years of age at time of test
Includes only first-time blood lead levels ≥ 5 ug/dL
Includes sample type of venous, capillary or unknown

September 23, 2015

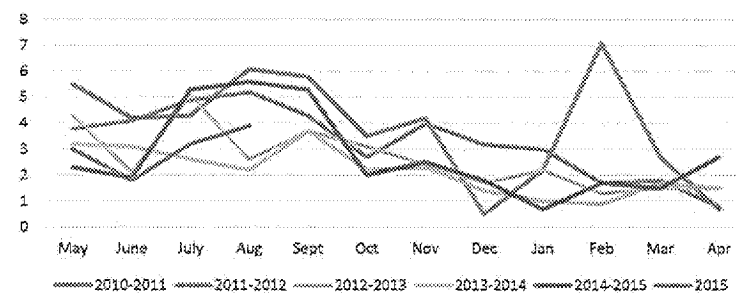
Source: MDHHS Data Warehouse, Lead Specimen table

City of Flint, Children less than 16 years of age
Tested for Lead Poisoning



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	402	379	325	442	504	315	335	206	276	240	338	285
2011-2012	390	370	324	503	512	413	372	248	333	298	389	370
2012-2013	328	335	376	540	458	416	331	237	325	298	325	397
2013-2014	371	353	378	401	432	414	305	277	304	319	363	339
2014-2015	346	324	379	445	471	357	281	219	301	287	342	337
2015	297	330	249	284								

City of Flint, Children less than 16 years of age
Percentage of Children Tested who had First-Time EBLL



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	5.5	4.2	4.3	6.1	5.8	3.5	4.2	0.5	2.2	7.1	2.7	0.7
2011-2012	3.8	4.1	4.9	5.2	4.3	2.7	4	3.2	3	1.7	1.8	0.8
2012-2013	4.3	2.1	5.1	2.6	3.7	3.1	2.4	1.7	2.2	1.3	1.5	1.5
2013-2014	3.2	3.1	2.6	2.2	3.7	2.2	2.3	1.4	1	0.9	1.7	1.5
2014-2015	2.3	1.9	5.3	5.6	5.3	2	2.5	1.8	0.7	1.7	1.5	2.7
2015	3	1.8	3.2	3.9								

Children Tested for Blood Lead Before and After the Change in Flint's Water Supply

Hurley tests only
(Provider ID = 00000252)

	Children Tested	Children with elevated blood lead levels									
		(Hurley analysis) Children		Venous only				All (V, C, unknown)			
		Tested	Pct ≥ 6	BLL ≥ 5	Pct ≥ 5	BLL ≥ 6	Pct ≥ 6	BLL ≥ 5	Pct ≥ 5	BLL ≥ 6	Pct ≥ 6
January 1 - September 15, 2013	1177	906	2.1	24	2.0	8	0.7	41	3.5	19	1.6
January 1 - September 15, 2015*	966	840	4.0	29	3.0	21	2.2	39	4	28	2.9

All Providers

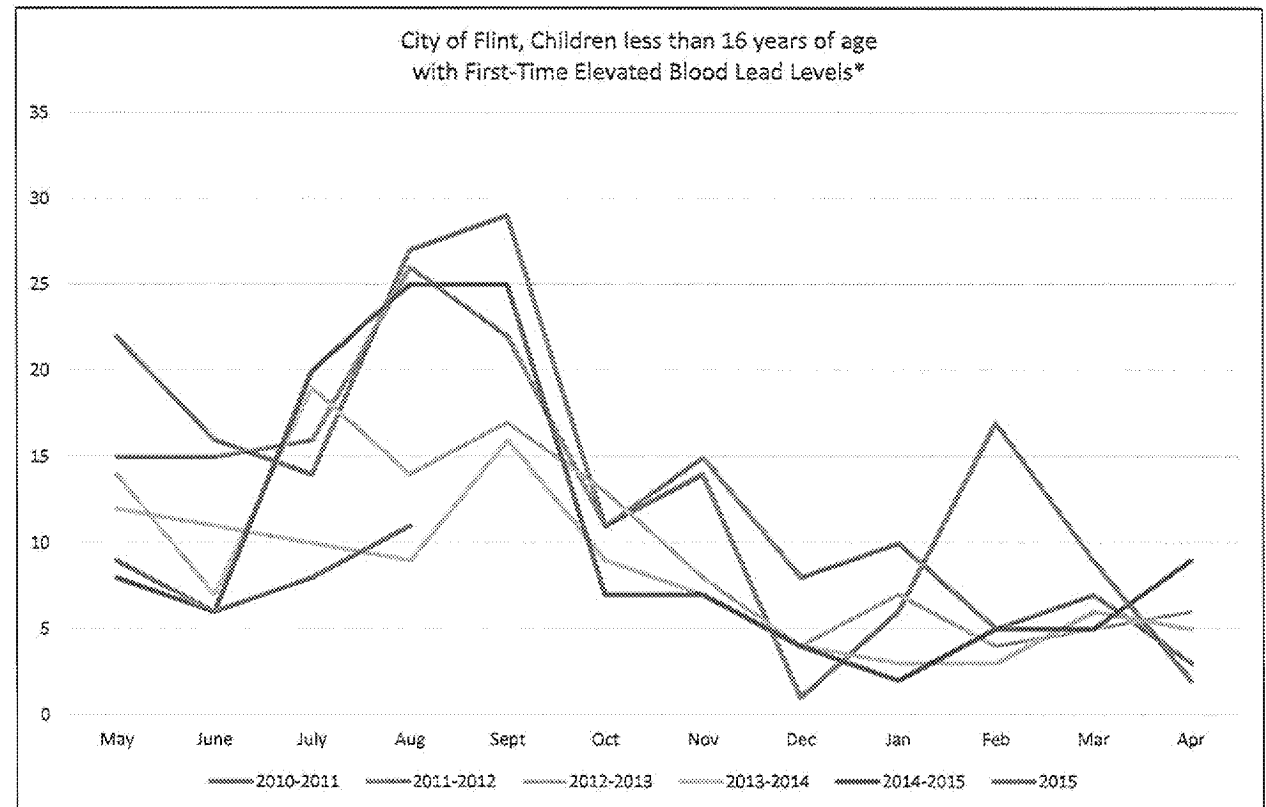
	Children Tested	Children with elevated blood lead levels									
		Venous only				All (V, C, unknown)					
		BLL ≥ 5	Pct ≥ 5	BLL ≥ 6	Pct ≥ 6	BLL ≥ 5	Pct ≥ 5	BLL ≥ 6	Pct ≥ 6	BLL ≥ 6	Pct ≥ 6
January 1 - September 15, 2013	2380	33	2.8	16	1.4	86	7.3	44	3.7		
January 1 - September 15, 2015*	1928	40	4.1	28	2.9	80	8.3	54	5.6		

Notes:
Children 0 - 5 years of age
Children living in zip codes 48501 -48507

Source: MDHHS Data Warehouse
September 24, 2015

Blood Lead Testing of Children in Flint, Before and After the Change in Flint's Water

- The change in Flint's water source occurred in April 2014. MDHHS looked at children's blood lead levels (BLL) before and after this event.
- The dark blue line (May 2014 – April 2015) and the green line (May-August 2015) reflect children's blood lead tests after the change. All other lines reflect tests before the change.
- An increase in childhood lead poisoning in summer (July, August, September) is typical throughout Michigan every year.
- While there is a dramatic difference between the numbers of elevated BLL in the summer before and after the event, a wider look that includes data back to 2010 shows that the year BEFORE the event (the yellow line) was more of an anomaly than the year after (the dark blue line).
- If elevated BLL were being driven by the change in water, we would expect the dark blue line to stay high rather than follow the seasonal pattern.
- All data included in this analysis were reported by laboratories directly to MDHHS, in accordance with State law.



*This graph includes:

Children whose address is listed as "Flint"--may not conform exactly to Flint city limits

Children less than 16 years of age at time of test

Only first-time blood lead levels ≥ 5 ug/dL

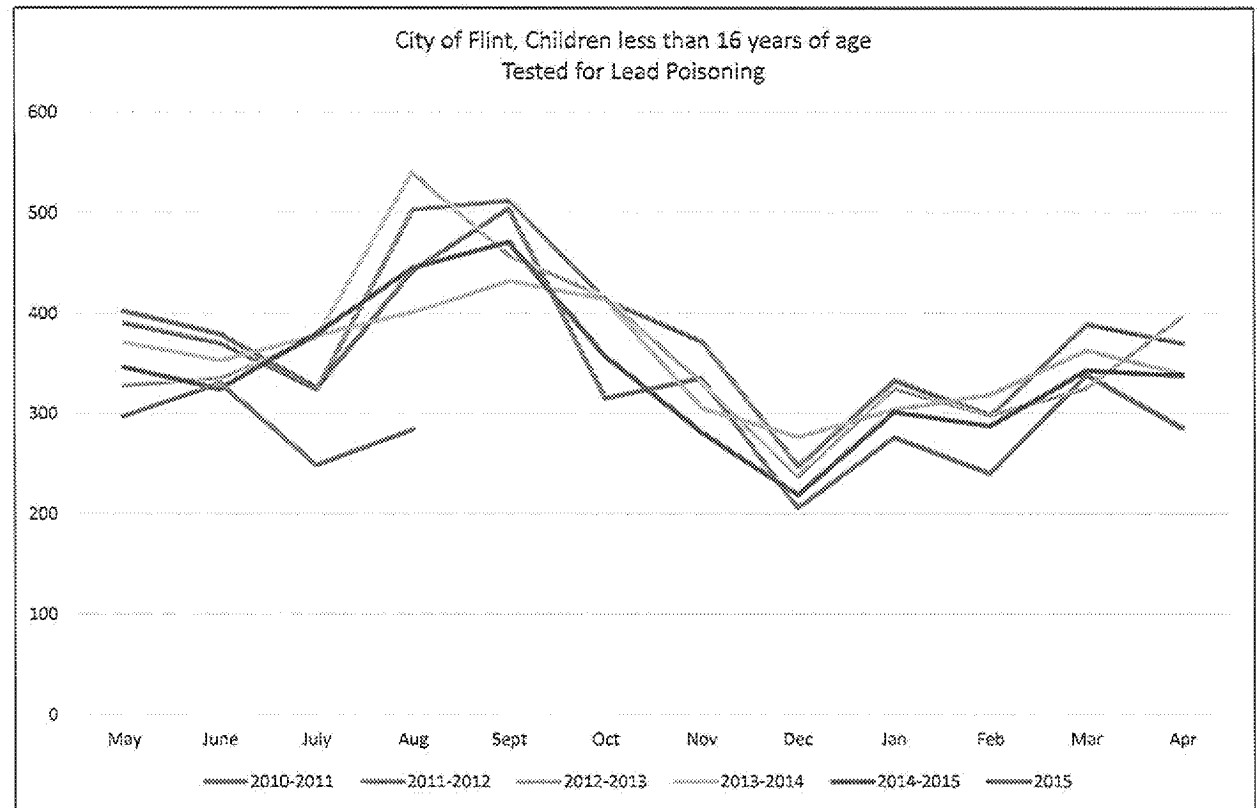
All first-time elevated levels, regardless of sample type (venous, capillary or unknown)

September 24, 2015

Source: MDHHS Data Warehouse,
Lead Specimen Table

Blood Lead Testing of Children in Flint, Before and After the Change in Flint's Water

- Blood lead testing (regardless of elevated levels) also tends to rise during late summer (August, September, October).
- This graph shows that testing in Flint has remained fairly steady over the last five years, except for a recent decline (May – August 2015).



*This graph includes:

Children whose address is listed as "Flint"—may not conform exactly to Flint city limits

Children less than 16 years of age at time of test

The number of children tested within each month.

Some children are tested more than once, and may be included in more than one month or year.

September 24, 2015

Source: MDHHS Data Warehouse,
Lead Specimen table

Children in Flint, less than 16 years of age, tested for lead

Children with Elevated BLL*

May 2010 - April 2011	168
2011-2012	153
2012-2013	118
2013-2014	95
2014-2015	123
May - August 2015	34

Children Tested**

May 2010 - April 2011	3,836
2011-2012	4,240
2012-2013	4,158
2013-2014	4,010
2014-2015	3,831
May - August 2015	1,143

*Each child counted only once.

**Some children counted in more than one year

September 24, 2015

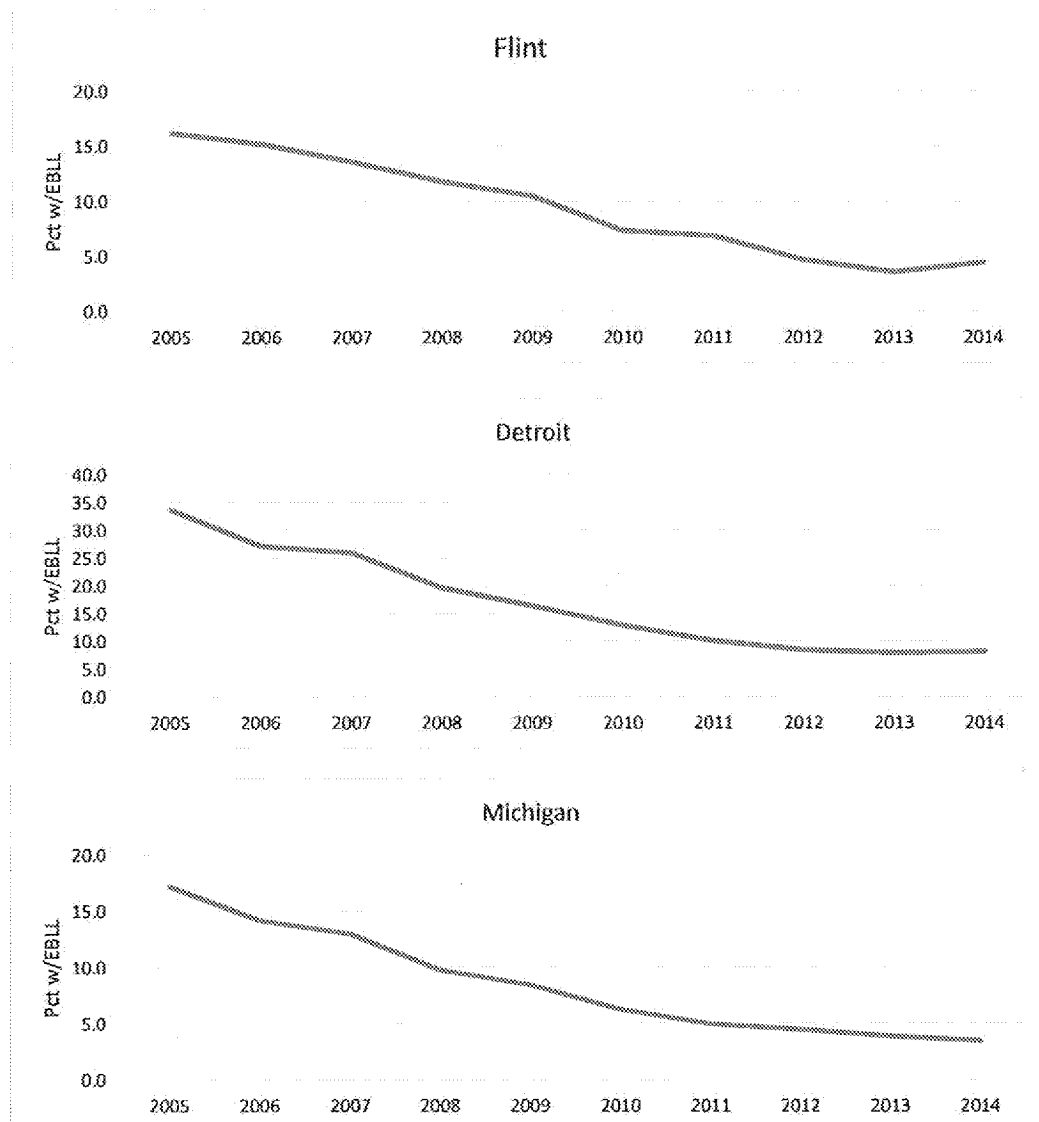
Source: MDHHS Data Warehouse

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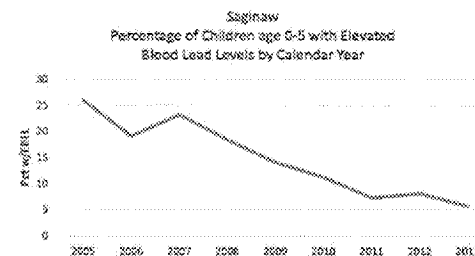
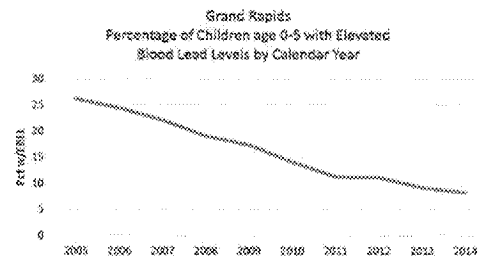
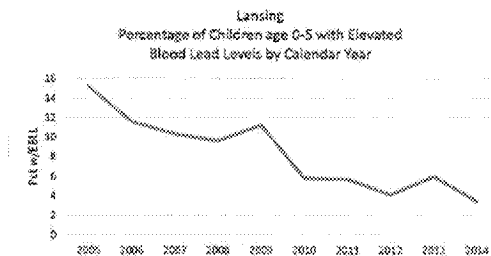
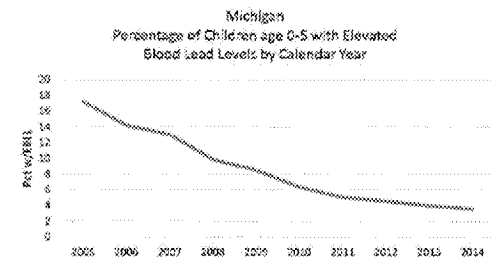
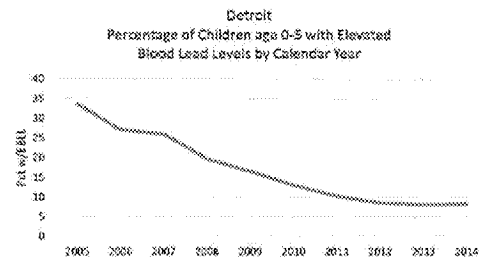
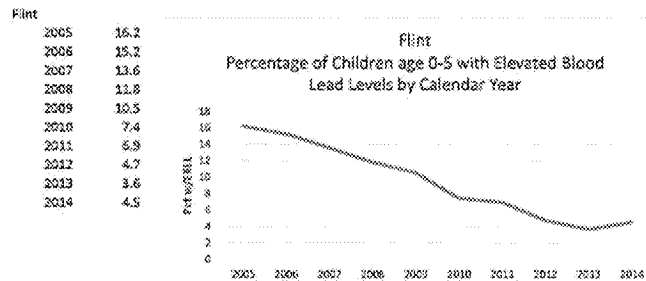
Percentage of Children age 0-5 with Elevated Blood Lead Levels by Calendar Year

Calendar Year	Flint			Detroit			Michigan		
	Children Tested	Number of Children ≥ 5*	Pct ≥ 5*	Children Tested	Number of Children ≥ 5*	Pct ≥ 5*	Children Tested	Number of Children ≥ 5*	Pct ≥ 5*
2005	3,076	499	16.2	32,704	11,032	33.7	132,913	22,843	17.2
2006	3,207	488	15.2	33,190	9,019	27.2	141,011	20,063	14.2
2007	2,950	401	13.6	33,010	8,571	26.0	149,445	19,496	13.0
2008	2,372	279	11.8	32,105	6,326	19.7	153,248	15,041	9.8
2009	2,321	244	10.5	31,969	5,266	16.5	154,291	13,161	8.5
2010	2,876	212	7.4	30,812	3,999	13.0	155,847	9,762	6.3
2011	2,349	162	6.9	28,674	2,928	10.2	151,867	7,547	5.0
2012	2,375	111	4.7	27,298	2,327	8.5	149,046	6,772	4.5
2013	2,345	85	3.6	25,026	1,996	8.0	147,841	5,702	3.9
2014	2,343	106	4.5	22,842	1,876	8.2	143,123	5,053	3.5

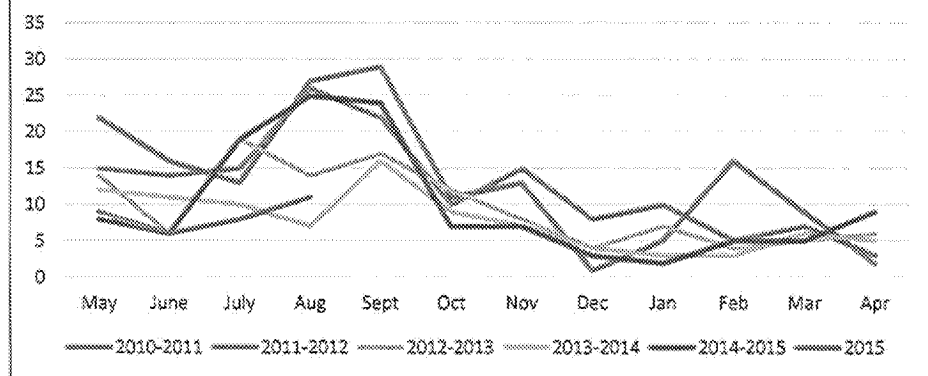
*Confirmed and unconfirmed



Flint	Detroit			Michigan			Lansing			Grand rapids			Saginaw					
Children Tested	C P Conf & n t S	Pct Conf & Unconf ≥ 5	Children Tested	Co nfi rm	Pct Conf & Unconf ≥ 5	Children Tested	Co nfi rm	Pct Conf & Unconf ≥ 5	tested	nbr	pct	tested	nbr	pct	tested	nbr	pct	
2005	3076	499	16.2	32704	11032	33.7	132913	22843	17.2	1934	294	15.2	5530	1447	26.2	1762	458	26
2006	3207	488	15.2	33190	9019	27.2	141611	20063	14.2	2512	291	11.6	5334	1299	24.4	1721	329	19.1
2007	2950	401	13.6	33010	8571	26	149445	19496	13	3539	366	10.3	4876	1100	22.3	1723	400	23.2
2008	1372	279	11.8	32105	6326	19.7	153248	15041	9.8	3330	321	9.6	4296	818	19	1697	313	18.4
2009	2321	344	10.5	31969	5266	16.5	154291	13161	8.5	3522	393	11.2	4084	708	17.3	1613	228	14.1
2010	2876	312	7.4	30812	3999	13	155847	9762	6.3	3373	196	5.8	4959	688	14.1	1828	207	11.3
2011	2349	162	6.9	28674	2928	10.2	151867	7547	5	3128	178	5.7	5185	579	11.2	1792	125	7.3
2012	2375	111	4.7	27298	2327	8.5	149046	6772	4.5	3121	129	4.1	4878	540	11.1	1628	132	8.1
2013	2345	85	3.6	25026	1996	8	147841	5701	3.9	3135	187	6	4639	426	9.2	1560	88	5.7
2014	2343 # 3	126	4.5	23842 # 7	1876	8.2	143123 # 2	5353	3.5	2995	103	3.4	4378	359	8.2			



City of Flint, Children less than 6 years of age
with First-Time Elevated Blood Lead Levels*



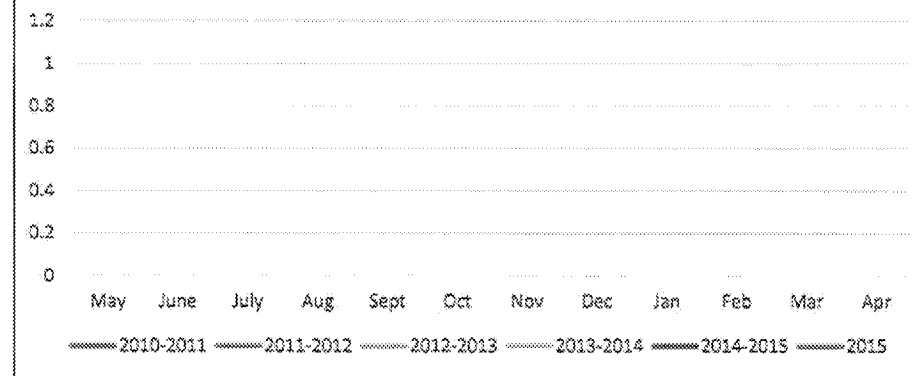
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	22	16	13	27	29	11	13	1	5	16	9	2
2011-2012	15	14	15	26	22	10	15	8	10	5	7	3
2012-2013	14	6	19	14	17	12	8	4	7	4	5	6
2013-2014	12	11	10	7	16	9	7	4	3	3	6	5
2014-2015	8	6	19	25	24	7	7	3	2	5	5	9
2015	9	6	8	11								

*Children whose address is listed as "Flint"--may not conform exactly to Flint city limits
 Less than 16 years of age at time of test
 Includes only first-time blood lead levels ≥ 5 ug/dL
 Includes sample type of venous, capillary or unknown

September 30, 2015

Source: MDHHS Data Warehouse, Lead Specimen table

City of Flint, Children less than 6 years of age
Tested for Lead Poisoning



	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2010-2011	0.22	0.16	0.13	0.27	0.29	0.11	0.13	0.01	0.05	0.16	0.09	0.02
2011-2012	0.15	0.14	0.15	0.26	0.22	0.10	0.15	0.08	0.10	0.05	0.07	0.03
2012-2013	0.14	0.06	0.19	0.14	0.17	0.12	0.08	0.04	0.07	0.04	0.05	0.06
2013-2014	0.12	0.11	0.10	0.07	0.16	0.09	0.07	0.04	0.03	0.03	0.06	0.05
2014-2015	0.08	0.06	0.19	0.25	0.24	0.07	0.07	0.03	0.02	0.05	0.05	0.09
2015	0.09	0.06	0.08	0.11								

Follow-up for Children in Flint (ZIPs 48501-48507) with Elevated Blood Lead Levels April 2014 through March 2015

Children with Initial Confirmed (Venous) Elevated BLL 5-14

Children w/BLL 5-14:	43
With retest:	14
Most recent retest was <5:	4
5 to 14:	9
>= 15:	1

Children with Initial Confirmed (Venous) Elevated BLL >= 15

Children w/BLL >= 15:	3
With retest:	1
Most recent retest was <5:	0
5 to 14:	0
>= 15:	1

Children with Initial Capillary Elevated BLL 5-14 (needing confirmation)

Children w/BLL 5-14:	70
With confirmatory venous:	15
Confirmatory test was <5:	7
5 to 14:	7
>= 15:	1

Children with Initial Capillary Elevated BLL >= 15 (needing confirmation)

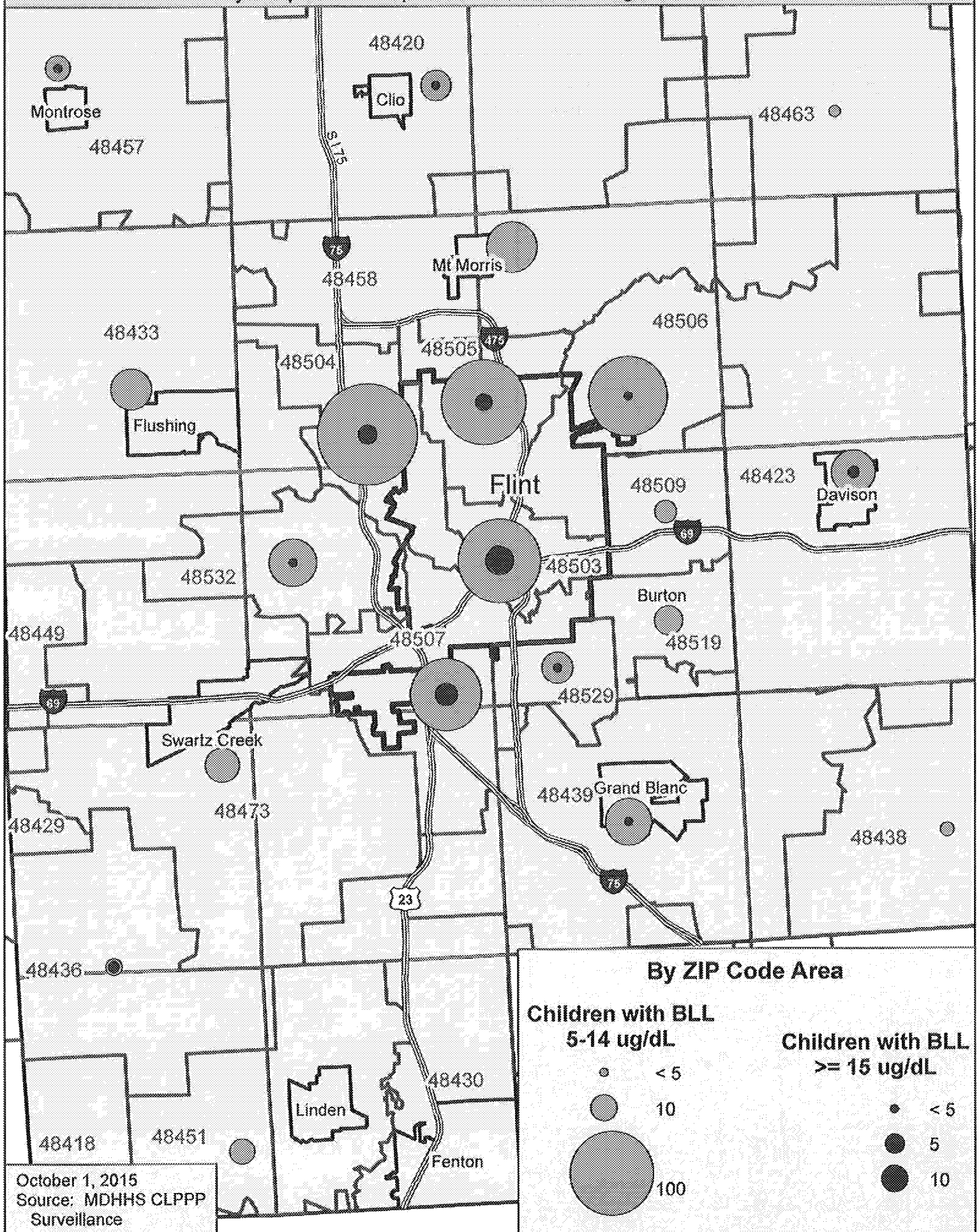
Children w/BLL >= 15:	1
With confirmatory venous:	0

October 5, 2015

Source: MDHHS Data Warehouse

Children with Elevated Blood Lead Levels in Genesee County, by ZIP Code Area

5-year period: September 1, 2010 - August 31, 2015



Children in Genesee County, Tested for Lead Poisoning, by Blood Lead Level

Most Recent 12-Month Period: September 1, 2014 - August 31, 2015

	0 - 4 ug/dL	5 - 14 ug/dL Confirmed*	5 - 14 ug/dL Not Confirmed*	15 - 44 ug/dL Confirmed*	15 - 44 ug/dL Not Confirmed*	>= 45 ug/dL
Flint ZIPS (48501-48507)	2,721	49	53	5	**	0
Genesee County (all ZIPS)	6,086	58	94	6	**	0

Most Recent Five-Year Period: September 1, 2010 - August 31, 2015

	0 - 4 ug/dL	5 - 14 ug/dL Confirmed*	5 - 14 ug/dL Not Confirmed*	15 - 44 ug/dL Confirmed*	15 - 44 ug/dL Not Confirmed*	>= 45 ug/dL
Flint ZIPS (48501-48507)	11,596	287	219	24	**	0
Genesee County (all ZIPS)	26,362	359	415	29	9	0

*One test per child is included in each table: the highest venous result, or if no venous, then the highest capillary result.

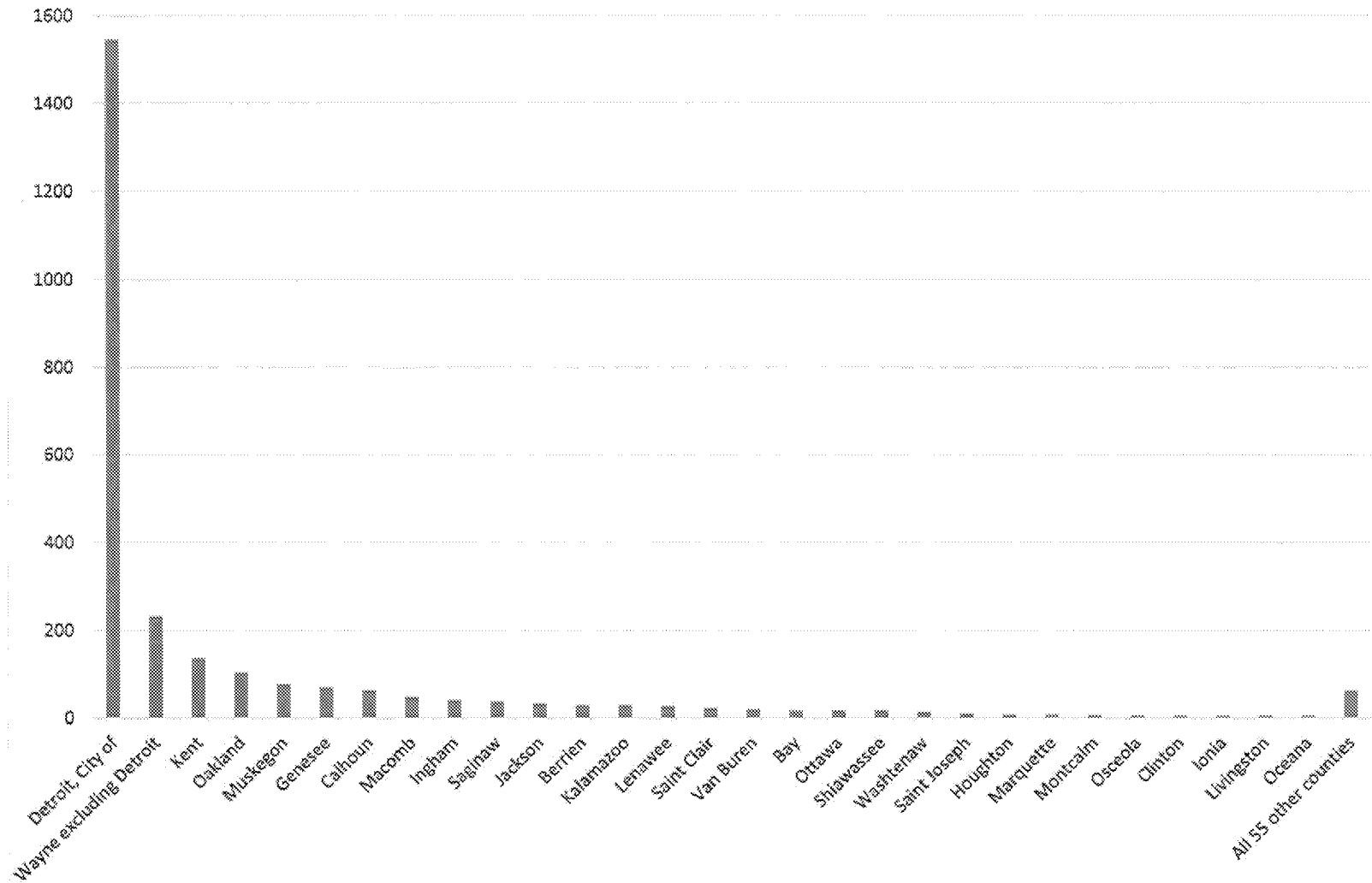
Only venous tests are considered to be "confirmed."

**Supressed (N<5)

October 1, 2015

Source: MDHHS CLPPP Surveillance

Children with Confirmed Elevated Blood Lead Levels ($\geq 5 \mu\text{g}/\text{dL}$) in CY 2014
by County and Detroit City



October 1, 2015

Source: MDHHS Data Warehouse

Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, September 08, 2015 4:19 PM
To: 'Marc Edwards'
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.
Attachments: DCH-1294 Data Use and Non-Disclosure Agreement 5-2015.doc

Marc,

Sorry I'm slow to get back to you. Yes, I think this sounds great. There has been some concern about the water source change in Flint, and in fact we had a call about it today. Yes, this will need a new data sharing agreement. Please fill out the attached and send back to me, leaving it as a Word document without signature. I'll run it past Legal, and they'll no doubt ask for a couple of changes.

Thanks,
 Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Wednesday, September 02, 2015 8:36 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Hi Robert,

I would like to repeat the study I did below, but updated for Flint Michigan, Genesee County Michigan, and Detroit. What I need is blood lead data from all Flint zip codes, Genesee County zip codes and Detroit zip codes from 2011 to present.

Please do not identify the records by name, but have an ID code for each individual that can be sorted, along with the date of the measurement, blood lead result, zip code in which the child resides, and child's birth date so I can determine the age of the subject.

The intervention of interest, is the change from Detroit water to Flint River water, in Flint Michigan. Genesee County and Detroit serve as control data sets.

If it can be provided in a format that can be read into EXCEL, that would be best.

Let me know if you need a new signed data sharing agreement, or whether our agreement from 2006 is still ok.

Best Regards,
Marc Edwards

Date: Fri, 17 Nov 2006 15:41:55 -0500
To: "Robert L. Scott" <scottrob@michigan.gov>
From: Marc Edwards <edwardsm@vt.edu>
Subject: Proposal and signed data agreement

Robert,

Attached is my signed agreement. My proposal is to do a study of potential benefits resulting from a community intervention in Lansing, MI.

Specifically, last year Lansing distributed drinking water filters and sent out enhanced flushing instructions to mitigate levels of lead in drinking water in homes with lead pipes. I am trying to determine whether this intervention had any discernable benefit on blood lead levels in the population.

To conduct this statistical test, I would like the following fields extracted from your database:

- 1) City of Lansing blood lead values, draw dates, and subject ID number from January 1 2001 to present. If you do not have accessible data starting in 2001, then go back as far as you can (e.g., 2002).
- 2) The same data for Ingham County (which I assume includes Lansing). If it is possible to get all data from within Ingham County but excluding Lansing that would be ideal. But I could presumably delete the duplicate data between set 1 and set 2 by hand if necessary.
- 3) The same data for the city of Detroit MI.

The statistical comparison will examine 1) temporal changes in % elevated blood lead for Lansing before and after the intervention, and 2) cross comparisons in trends between Lansing (with intervention) and Detroit and Ingham County (without intervention).

This is a fairly straightforward test that I suspect will confirm that no significant change arose due to the intervention in Lansing, consistent with water as a minor contributor to blood lead in Lansing.

If you should have additional questions please e-mail me at this address or call me at 540 231-7236,

Regards,
Marc Edwards

At 03:14 PM 11/17/2006, Robert L. Scott wrote:
Thanks for the info. Please see attached. Just a reminder that a "proposal" is also required. It need not be particularly long or formal, but should indicate clearly the data requested, and what you intend to do with it.

Scott, Robert L. (DHHS)

From: Marc Edwards <edwardsm@vt.edu>
Sent: Tuesday, September 08, 2015 5:39 PM
To: Scott, Robert L. (DCH)
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.
Attachments: DCH-1294 Data Use and Non-Disclosure Agreement 5-2015.doc; 94 DC_Water_Lead_Edwards_2009.pdf; Rapid Proposal Final.pdf

Here you go.

Best Regards,
 Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Tuesday, September 08, 2015 7:55 AM
To: Marc Edwards
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Yes, sorry for the delay; I'll get you a more complete answer later today.

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Monday, September 07, 2015 11:40 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: FW: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Robert,

Can you confirm that you received the e-mail below, with the request for blood lead data on Flint?

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From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Wednesday, September 2, 2015 8:36 PM
To: 'scottrob@michigan.gov' <scottrob@michigan.gov>
Subject: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Hi Robert,

I would like to repeat the study I did below, but updated for Flint Michigan, Genesee Country Michigan, and Detroit. What I need is blood lead data from all Flint zip codes, Genesee County zip codes and Detroit zip codes from 2011 to present.

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If it can be provided in a format that can be read into EXCEL, that would be best.

Let me know if you need a new signed data sharing agreement, or whether our agreement from 2006 is still ok.

Best Regards,
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Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:09 PM
To: Peeler, Nancy (DCH); 'Lishinski Karen (LishinskiK@michigan.gov)'; Priem, Wesley F. (DCH)
Subject: Flint water study
Attachments: Rapid Proposal Final.pdf

Nancy, Karen and Wes,

I'm passing this along as follow-up to our previous attention to the Flint water changeover situation. The attached was submitted to me along with a request for de-identified data, which should be no problem.

When you have a few minutes you might want to take a look at it. Sounds like there might be more to this than what we learned previously. Yikes!

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Pending Data Sharing
Agreements

Organization/Individual	Date Initiated	Have I responded?	Status	IRB Status	Date last action	MOU developed?
Center for Urban Studies	6/2/2015	yes	discussed with Colin		7/2/2015	no
ClearCorp	6/4/2015	yes	discussed with Colin		7/2/2015	no
Gazze/MIT	6/3/2015	yes	discussed with Colin		7/2/2015	no
DDD	6/8/2015	yes	discussed with Colin		8/11/2015	no
Moody & Grady, MSU	6/23/2015	yes	resubmitted to Colin		8/25/2015	no
Tanaka/Tufts	8/5/2015	yes	submitted to Colin		8/27/2015	no
McEmurry, WSU	9/8/2015	yes	returned to McEmurry		9/9/2015	no
Edwards, Virginia Tech	9/7/2015	yes				request was withdrawn
Hanna-Attisha, Hurley	9/22/2015	yes	Approved	Approved	10/2/2015	no

8/3/15 still waiting for LG to send MIT IRB
I sent email asking for changes, also suggesting wait for Kaplowitz/Larder work. Kit left phone message, I sent email explaining the project.

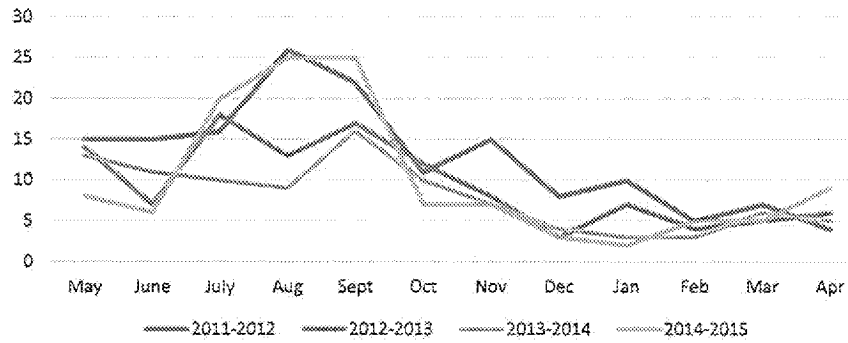
Sent feedback to Heather, asking for revised DCH-1204 and letter, MSU IRB app, and MDCH IRB app.

Nudge Colin when you got IRB response.

8/25/15
made a

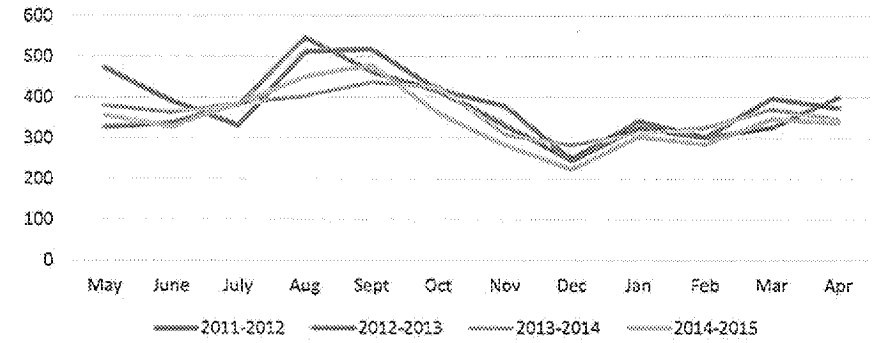
Data sent

City of Flint, Children less than 16 years of age
with First-Time Elevated Blood Lead Levels



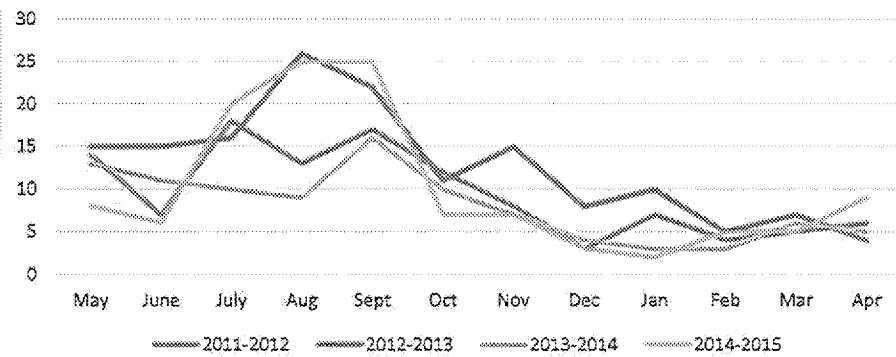
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2011-2012	15	15	16	26	22	11	15	8	10	5	7	4
2012-2013	14	7	18	13	17	12	8	3	7	4	5	6
2013-2014	13	11	10	9	16	10	7	4	3	3	6	5
2014-2015	8	6	20	25	25	7	7	3	2	5	5	9

City of Flint, Children less than 16 years of age
Tested for Lead Poisoning



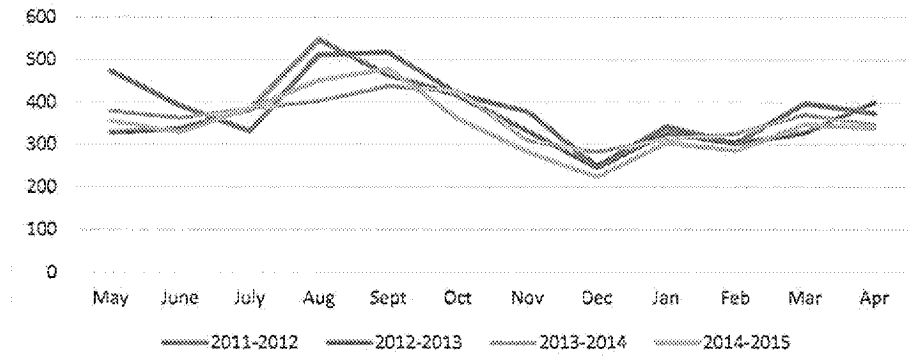
	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
2011-2012	474	393	332	513	520	420	379	249	343	303	399	375
2012-2013	328	338	383	550	464	417	332	246	328	303	328	402
2013-2014	380	363	385	404	438	427	310	283	313	325	371	346
2014-2015	356	329	386	452	480	361	283	224	305	287	348	339

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Date	Elevated	Tested	Proportion	Mean P	P LCL	P UCL
May-13	13	380	0.034	0.022	0	0.04
Jun-13	11	363	0.030	0.022	0.00	0.04
Jul-13	10	385	0.026	0.022	0.00	0.04
Aug-13	9	404	0.022	0.022	0.00	0.04
Sep-13	16	438	0.037	0.022	0.00	0.04
Oct-13	10	427	0.023	0.022	0.00	0.04
Nov-13	7	310	0.023	0.022	0.00	0.04
Dec-13	4	283	0.014	0.022	0.00	0.04
Jan-14	3	313	0.010	0.022	0.00	0.04
Feb-14	3	325	0.009	0.022	0.00	0.04
Mar-14	6	371	0.016	0.022	0.00	0.04
Apr-14	5	346	0.014	0.022	0.00	0.04
May-14	8	356	0.022	0.022	0.00	0.04
Jun-14	6	329	0.018	0.022	0.00	0.04
Jul-14	20	386	0.052	0.022	0.00	0.04
Aug-14	25	452	0.055	0.022	0.00	0.04
Sep-14	25	480	0.052	0.022	0.00	0.04
Oct-14	7	361	0.019	0.022	0.00	0.04
Nov-14	7	283	0.025	0.022	0.00	0.04
Dec-14	3	224	0.013	0.022	0.00	0.04
Jan-15	2	305	0.007	0.022	0.00	0.04
Feb-15	5	287	0.017	0.022	0.00	0.04
Mar-15	5	348	0.014	0.022	0.00	0.04
Apr-15	9	339	0.027	0.022	0.00	0.04

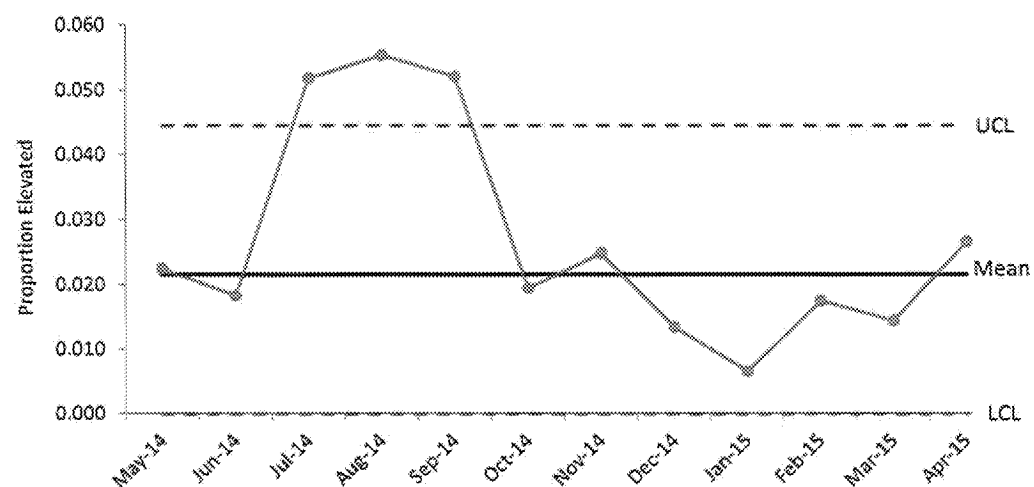
2013/14
Mean P 0.022
Mean n 362.08

$\hat{p}$ -chart

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$

Center Line: $\bar{p}$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$



Scott, Robert L. (DHHS)

From: Marc Edwards <edwardsm@vt.edu>
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Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:26 PM
To: Boes, Colin (DCH)
Subject: New DCH-1294, time-sensitive
Attachments: DCH-1294 Data Use and Non-Disclosure Agreement Edwards 091115.doc; Rapid Proposal Final.pdf

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Marc,

OK, I submitted your request including your proposal and the paragraph below. No guarantees on the timing, though.

I've attached a copy of the DCH-1294 here, because I made a few edits based on my previous experience with the review process.

Bob

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Subject: FW: New DCH-1294, time-sensitive

Marc,

(I also left you a phone message.) Please see below regarding an IRB review application. I told Colin that, as far as I know, our IRB director is expected back on Monday.

Have you submitted an IRB review application to Virginia Tech's IRB? If so, has it been approved? If that's the case, you can submit an Abbreviated IRB review app to MDHHS. It's available at www.michigan.gov/IRB.

If you haven't and don't intend to, please send me yet another paragraph explaining why not. I'm not an expert on these matters, and I'm still a little fuzzy on when an IRB review is required.

There is far more scrutiny of all data requests now than in 2006. That's a good thing in the long run, but makes it harder to move quickly.

Bob

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 1:33 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert, thank you for letting me know about the time-sensitivity. I will do my best to get this turned around as soon as I can. Since this involves research you may wish to send it the IRB as well and let them know about the urgency. How soon do you think they were hoping to get it back? A few weeks? Shorter? I ask because our IRB director Ian is out of the office until at least next week (I cannot remember exactly how long he is out).

Colin Boes, JD
 Privacy Specialist
 Office of Legal Affairs & FOIA
 Michigan Department of Health & Human Services
 201 Townsend St.
 Lansing, Michigan 48933
 (517) 335-8558 – T (517) 241-1200 - F

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Prof. Marc Edwards, Virginia Tech

From: Priem, Wesley F. (DCH)
Sent: Friday, September 11, 2015 2:34 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Flint water study

I know when I share this with my Division Director Linda Dykema she will also want to know who sent the request in to you. She has been involved in this issue.

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 2:08 PM
To: Priem, Wesley F. (DCH); Peeler, Nancy (DCH); Lishinski, Karen (DCH)
Subject: RE: Flint water study

Yes, it looks that way, but that's how I received it.

From: Priem, Wesley F. (DCH)
Sent: Friday, September 11, 2015 1:57 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Peeler, Nancy (DCH) <PeelerN@michigan.gov>; Lishinski, Karen (DCH) <LishinskiK@michigan.gov>
Subject: RE: Flint water study

Bob:

Was this all that was sent to you, looks like the cover page is missing?

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:09 PM
To: Peeler, Nancy (DCH); Lishinski, Karen (DCH); Priem, Wesley F. (DCH)
Subject: Flint water study

Nancy, Karen and Wes,

I'm passing this along as follow-up to our previous attention to the Flint water changeover situation. The attached was submitted to me along with a request for de-identified data, which should be no problem.

When you have a few minutes you might want to take a look at it. Sounds like there might be more to this than what we learned previously. Yikes!

Robert L. Scott
 Childhood Lead Poisoning Prevention Program

Michigan Department of Health & Human Services

(517) 335-8178

fax (517) 335-8509

Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, September 15, 2015 9:18 AM
To: 'Marc Edwards'
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Marc,

Turns out you should submit an IRB review application to MDHHS. The application is available at www.michigan.gov/irb. It should be submitted to me, and then I'll add my info as "responsible employee" and submit it to the IRB board.

Bob

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Friday, September 11, 2015 1:03 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Yes, I think there is clearly some urgency to the situation.

MDEQ has publicly stated that your blood lead records, are showing that there is no public health concern for residents in Flint.

The levels of lead in Flint water, that we are finding in our water sampling, are certainly in a range that can cause childhood lead poisoning.

Indeed, one child has already, likely been lead poisoned from exposure to high lead in water.

I think the fact that you already have other teams working on these records, indicates a high level of interest, and urgency.

Congressional interest in the safety of the water is also very high, and this will be an important issue in deciding options for treating the water, in the weeks and months ahead.

Best Regards,

Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Friday, September 11, 2015 12:58 PM
To: Marc Edwards
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Maybe. My contact at Legal let me know the other day that he's unusually busy with other matters right now, so his review of DUAs might be delayed unless there was a specific reason for quicker action on his part.

If you are in need of a reasonably-quick turnaround—i.e., a week rather than a month or so—then please send me a paragraph explaining why. I'll pass that along with your DUA.

If you're not in a hurry, then I'm all set for now—I'll submit your DUA as is.

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 10, 2015 7:57 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Do you need anything else from me?
 Marc

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Tuesday, September 08, 2015 5:39 PM
To: 'Scott, Robert L. (DCH)'
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Here you go.

Best Regards,
 Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Tuesday, September 08, 2015 7:55 AM
To: Marc Edwards
Subject: RE: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Yes, sorry for the delay; I'll get you a more complete answer later today.

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Monday, September 07, 2015 11:40 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: FW: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Robert,

Can you confirm that you received the e-mail below, with the request for blood lead data on Flint?

Marc

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Wednesday, September 2, 2015 8:36 PM
To: 'scottrob@michigan.gov' <scottrob@michigan.gov>
Subject: Repeat of 2006 study request, but for Flint and Genesee County and Detroit zip codes, from January 1 2011 to present.

Hi Robert,

I would like to repeat the study I did below, but updated for Flint Michigan, Genessee Country Michigan, and Detroit.

What I need is blood lead data from all Flint zip codes, Genesee County zip codes and Detroit zip codes from 2011 to present.

Please do not identify the records by name, but have an ID code for each individual that can be sorted, along with the date of the measurement, blood lead result, zip code in which the child resides, and child's birth date so I can determine the age of the subject.

The intervention of interest, is the change from Detroit water to Flint River water, in Flint Michigan. Genesee County and Detroit serve as control data sets.

If it can be provided in a format that can be read into EXCEL, that would be best.

Let me know if you need a new signed data sharing agreement, or whether our agreement from 2006 is still ok.

Best Regards,
Marc Edwards

Date: Fri, 17 Nov 2006 15:41:55 -0500
To: "Robert L. Scott" <scottrob@michigan.gov>
From: Marc Edwards <edwardsm@vt.edu>
Subject: Proposal and signed data agreement

Robert,

Attached is my signed agreement. My proposal is to do a study of potential benefits resulting from a community intervention in Lansing, MI.

Specifically, last year Lansing distributed drinking water filters and sent out enhanced flushing instructions to mitigate levels of lead in drinking water in homes with lead pipes. I am trying to determine whether this intervention had any discernable benefit on blood lead levels in the population.

To conduct this statistical test, I would like the following fields extracted from your database:

- 1) City of Lansing blood lead values, draw dates, and subject ID number from January 1 2001 to present. If you do not have accessible data starting in 2001, then go back as far as you can (e.g., 2002).
- 2) The same data for Ingham County (which I assume includes Lansing). If it is possible to get all data from within Ingham County but excluding Lansing that would be ideal. But I could presumably delete the duplicate data between set 1 and set 2 by hand if necessary.
- 3) The same data for the city of Detroit MI.

The statistical comparison will examine 1) temporal changes in % elevated blood lead for Lansing before and after the intervention, and 2) cross comparisons in trends between Lansing (with intervention) and Detroit and Ingham County (without intervention).

This is a fairly straightforward test that I suspect will confirm that no significant change arose due to the intervention in Lansing, consistent with water as a minor contributor to blood lead in Lansing.

If you should have additional questions please e-mail me at this address or call me at 540 231-7236,

Regards,
Marc Edwards

At 03:14 PM 11/17/2006, Robert L. Scott wrote:
Thanks for the info. Please see attached. Just a reminder that a
"proposal" is also required. It need not be particularly long or
formal, but should indicate clearly the data requested, and what you
intend to do with it.

Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Tuesday, September 15, 2015 9:21 AM
To: 'Marc Edwards'
Subject: FW: New DCH-1294, time-sensitive

Marc,

Please see Colin's (Legal Affairs) comments below. I apologize for not passing it along yesterday—the day got away from me. I clearly have a lot to learn—I made changes to your document thinking it was a slam-dunk as de-identified, but was wrong, as indicated below.

Please make changes to your DCH-1294 as directed by Colin's comments, and re-submit to me, still no signature.

Thanks,
 Bob

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 2:08 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Horste, Ian (DCH) <Horstel@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert,

Here are my comments regarding this DUA. Please feel free to give me a call if you have any questions. As I indicate below, we also need to see about whether our IRB needs to be involved.

1. I want to know more about the study that is being recreated in item 1. The attached protocol seems to discuss more about the study of the water samples, not the blood lead data. Saying that the researcher wants to verify the claim of MDEQ is not sufficient. It does not have to be a great deal longer, but it should explain what the intended use of the blood lead data is.

It is also important to know exactly how it will be used for research in order to justify the release not just under HIPAA, but also under R 325.9086 pertaining to the confidentiality of blood lead test reports. It must be for the "If necessary for the purpose of research designed to develop or contribute to generalizable knowledge, with documented approval by the department's institutional review board." R 325.9086(2)(e). I am not sure how Ian would handle this, given the language in the rule that seems to require IRB approval.

2. Tying in with 1. above, telling us that the analysis will be similar to some other study is insufficient. This section should tell us how the data will be used and disclosed, how many people (research team) might have access, what formats it might be used in and other similar information. The attached research protocol, as noted above, does not get into sufficient detail regarding exactly how our blood lead data will be used and how its use will be restricted.

I also need to know more about how the data will be secured on their end, how it will be handled, by who, and what will be done with it when it is no longer needed for their study.

3. The researcher indicates this data will be deidentified, but then goes on to ask for a number of identifiers that make the data identifiable, including county, city, and birth date of the child. In order for data to be deidentified (short of the statistical analysis method which would have to be documented and shown to us), it must not contain any geographic subdivision smaller than state, 45 CFR 164.414(b)(2)(i)(B). Additionally, all elements of dates related to the individual must not be included, which includes birth date, 45 CFR 164.414(b)(2)(i)(C). Therefore, the researcher must follow protocols for identifiable data, which may include requesting a waiver of informed consent from the IRB.

The researcher could possibly obtain the data requested as a limited data set without a waiver I believe (though we still would want to run it by the IRB). If this is the case, item 3.b. should be changed to "Limited Data Set."

Colin Boes, JD
Privacy Specialist
Office of Legal Affairs & FOIA
Michigan Department of Health & Human Services
201 Townsend St.
Lansing, Michigan 48933
(517) 335-8558 – T (517) 241-1200 - F

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:44 PM
To: Boes, Colin (DCH)
Subject: RE: New DCH-1294, time-sensitive

Thanks. I was told by a colleague of mine that Ian is expected back on Monday (I hope she was right).

I think the researcher is hoping for a turn-around with a week or so, but I'm sure he knows he can't make (and hasn't made) demands. I'll check with him about an IRB.

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 1:33 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert, thank you for letting me know about the time-sensitivity. I will do my best to get this turned around as soon as I can. Since this involves research you may wish to send it the IRB as well and let them know about the urgency. How soon do you think they were hoping to get it back? A few weeks? Shorter? I ask because our IRB director Ian is out of the office until at least next week (I cannot remember exactly how long he is out).

Colin Boes, JD
Privacy Specialist
Office of Legal Affairs & FOIA
Michigan Department of Health & Human Services
201 Townsend St.
Lansing, Michigan 48933
(517) 335-8558 – T (517) 241-1200 - F

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:26 PM
To: Boes, Colin (DCH)
Subject: New DCH-1294, time-sensitive

Colin,

Please see attached DUA and related proposal. I'm asking for a reasonably-quick turn-around on this request for de-identified data, if possible given your schedule. I've pasted Professor Edwards' comments below:

"Yes, I think there is clearly some urgency to the situation.

MDEQ has publicly stated that your blood lead records, are showing that there is no public health concern for residents in Flint.

The levels of lead in Flint water, that we are finding in our water sampling, are certainly in a range that can cause childhood lead poisoning.

Indeed, one child has already, likely been lead poisoned from exposure to high lead in water.

I think the fact that you already have other teams working on these records, indicates a high level of interest, and urgency.

Congressional interest in the safety of the water is also very high, and this will be an important issue in deciding options for treating the water, in the weeks and months ahead."

Thanks,
Bob

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Wednesday, September 16, 2015 10:48 AM
To: Lawrence Reynolds; Mona Hanna-Attisha; Laura Carravallah; Dr. Lawrence Reynolds, M.D.
Cc: Peeler, Nancy (DCH); Lishinski, Karen (DCH); Emily Houk (emily@r2pconsultants.com); Scott, Robert L. (DCH)
Subject: RE: Lead level data

Dr. Reynolds,

I'll be happy to slice up the data in that way, including the most recent months available. I'll be out of the office for the next few days, but will work on it when I get back.

It's my understanding that the State will develop a fact sheet as well as a tip sheet on lead-safe water use for parents. I'm not sure how they'll be made public.

Thanks,
 Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Lawrence Reynolds [mailto:lrey52@gmail.com]
Sent: Wednesday, September 16, 2015 10:31 AM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Mona Hanna-Attisha <MHanna1@hurleymc.com>; Laura Carravallah <lcarrav1@yahoo.com>; Dr. Lawrence Reynolds, M.D. <reynolds@mottchc.org>
Subject: Lead level data

Good morning Mr. Scott .

Thank you for your timely response.I have reviewed the graphs with our GCHD and Dr. Mona Hanna-Attisha of Hurley.Is it possible to stratify the data by age -under 15 months, 16 months to under 6 years of age , over 6 years.Also can we get the most recent data for 2015.

At this point we will work with our patients to educate them.

Breast feeding is first choice .

I understand different filters do different things for lead , and not all get lead clumps from leaching pipes so we will not emphasize them.

We will try to get WIC to cover bottled water and encourage using water from outside the city system

Our goal is to give the most consistent correct information.

Are there any plans for public service announcements from the state ?

I am asking you to cc my ~~YGolds@mcchgo~~ email along with lreys2@ gmail so I can access from anywhere.

--

Lawrence Reynolds

Scott, Robert L. (DHHS)

From: Mona Hanna-Attisha <MHanna1@hurleymc.com>
Sent: Wednesday, September 16, 2015 3:10 PM
To: Scott, Robert L. (DCH)
Cc: Lawrence Reynolds
Subject: FW: IRBNet Board Action
Attachments: IRBNetDocument (33).pdf; Study Proposal IRB BLL MHA.pdf

Bob, I just received IRB approval to look at the City of Flint blood lead levels. I would love to get the raw data if that is possible. Attached is my study proposal and the IRB approval.

Specific fields that we are looking for include:

MCIR ID or some sort of identifier to ensure first time lead level only Zip code Date of Birth Date of Blood lead level Lead level

Would greatly appreciate your assistance! Thanks!

Mona Hanna-Attisha MD MPH FAAP
 Program Director Pediatric Residency
 Hurley Children's Hospital at Hurley Medical Center Michigan State University College of Human Medicine Department of Pediatrics and Human Development Mhanna1@hurleymc.com

-----Original Message-----

From: Nicolas Lecea [mailto:no-reply@irbnet.org]
Sent: Wednesday, September 16, 2015 2:09 PM
To: Jenny LaChance; Mona Hanna-Attisha
Subject: IRBNet Board Action

Please note that Hurley Medical Center Institutional Review Board has taken the following action on IRBNet:

Project Title: [807433-1] Analysis of Pediatric Blood Lead Levels Principal Investigator: Mona Hanna-Attisha, MD MPH

Submission Type: New Project
 Date Submitted: September 15, 2015

Action: APPROVED
 Effective Date: September 16, 2015
 Review Type: Expedited Review

Should you have any questions you may contact Nicolas Lecea at nlecea1@hurleymc.com.

Thank you,
 The IRBNet Support Team

Scott, Robert L. (DHHS)

From: Peeler, Nancy (DCH)
Sent: Wednesday, September 16, 2015 4:14 PM
To: Scott, Robert L. (DCH); Lishinski, Karen (DCH); Emily Houk R2P (emily@r2pconsultants.com)
Cc: Smith, Jennifer (DCH)
Subject: FW: MI lead POC

FYI - Jen, this is part of why we are working on talking points. Because of this, I imagine we'll want to include points about what our program offers/can do.

-----Original Message-----

From: Credle, Kimball (CDC/ONDIEH/NCEH) [mailto:kfc2@cdc.gov]
Sent: Wednesday, September 16, 2015 3:39 PM
To: Merkle, Sarah (CDC/ONDIEH/NCEH)
Cc: Peeler, Nancy (DCH)
Subject: RE: MI lead POC

Sure!

The POC there is Nancy Peeler. Her phone number and email address is (517)335-9230 - peelern@michigan.gov

I spoke with her last week about this issue and she assured me that they were complying with local inquiries and providing the necessary support.

Kimball F. Credle, MPH
 Public Health Advisor
 Healthy Homes and Lead Poisoning Prevention Program CDC, NCEH, EEHS
 4770 Buford Highway (MS - F58)
 Atlanta, GA. 30341
 (770)488-3643 Office
 (770)488-3635 Fax
PPI Cell

kc

-----Original Message-----

From: Merkle, Sarah (CDC/ONDIEH/NCEH)
Sent: Wednesday, September 16, 2015 12:09 PM
To: Credle, Kimball (CDC/ONDIEH/NCEH) <kfc2@cdc.gov>
Cc: Brown, Mary Jean (CDC/ONDIEH/NCEH) <mjb5@cdc.gov>
Subject: MI lead POC

Hi Kimball,

I've been working with OPPE and Mary Jean on a a congressional inquiry about lead in water in Flint, MI.

Could you please send me the MI lead program POC?

Thanks!

Sarah

Sarah Merkle, MPH

Associate Director for Policy || Division of Emergency and Environmental Health Services (DEEHS) || CDC - National Center for Environmental Health

Phone: 770-488-0541 || Email: smerkle@cdc.gov || Cell: PPI

Scott, Robert L. (DHHS)

From: Smith, Jennifer (DCH)
Sent: Wednesday, September 16, 2015 4:19 PM
To: Peeler, Nancy (DCH); Scott, Robert L. (DCH); Lishinski, Karen (DCH); Emily Houk R2P (emily@r2pconsultants.com)
Cc: Lasher, GERALYN (DCH); Minicuci, Angela (DCH); Hertel, Elizabeth (DCH)
Subject: RE: MI lead POC

Thanks Nancy. I'm looping in GERALYN, Angela, and Elizabeth as a heads up about the congressional hearing.

Do you know when the hearing is taking place? Is DEQ involved?

Thank you,
 Jennifer

-----Original Message-----

From: Peeler, Nancy (DCH)
Sent: Wednesday, September 16, 2015 4:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Lishinski, Karen (DCH) <LishinskiK@michigan.gov>; Emily Houk R2P (emily@r2pconsultants.com) <emily@r2pconsultants.com>
Cc: Smith, Jennifer (DCH) <smithj32@michigan.gov>
Subject: FW: MI lead POC

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Cc: Lasher, GERALYN (DCH); Minicuci, Angela (DCH); Hertel, Elizabeth (DCH)
Subject: RE: MI lead POC

I don't have any details other than what I forwarded, sorry. The Congressional piece is new information for me. If I hear from the CDC person, I will pass along whatever I learn from him/her.

-----Original Message-----

From: Smith, Jennifer (DCH)
Sent: Wednesday, September 16, 2015 4:19 PM
To: Peeler, Nancy (DCH); Scott, Robert L. (DCH); Lishinski, Karen (DCH); Emily Houk R2P (emily@r2pconsultants.com)
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Subject: FW: MI lead POC

FYI - Jen, this is part of why we are working on talking points. Because of this, I imagine we'll want to include points about what our program offers/can do.

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Could you please send me the MI lead program POC?

Thanks!

Sarah

Sarah Merkle, MPH

Associate Director for Policy || Division of Emergency and Environmental Health Services (DEEHS) || CDC - National Center for Environmental Health

Phone: 770-488-0541 || Email: smerkle@cdc.gov || Cell: [PPI]

12 October 2015
DRAFT MDHHS Flint Water Action Plan

Last Updated: 11:30 AM on October 12, 2015			
Action	Local Lead	MDHHS Lead	Tasks
Filter/Water Distribution	United Way (current) A local lead needs to be identified to head distribution operations (possibly with the LHD)*	E. Hertel (filters) It is possible that Richard Thelen may be the new MDHHS lead; requires further discussion*	Eden to talk to Jamie: - Coordination - Tracking filters - Ordering filter replacements - Identify a local lead
Blood Testing (venous preferable; confirm with Linda Dykema or do we want capillary testing?)	Needs to be identified* Possible partners: - Hurley - Great Flint Health Coalition - MIHP - LHD - Schools	Linda Dykema	- Identification of all current positives (retest) - Test all (capillary v. venous testing?*) - o Students 0-16 - o Priorities: ▪ 3 schools ▪ 2 zip codes ▪ ages 0-15 - Partner with schools - Partner with Great Flint Health Coalition - Partner with Hurley - Partner with LHD - Partner with MIHP (Medicaid) - Confirm that the state lab has capacity to handle increase in tests
Elevated Blood Level Investigations(all > 5 mg/dl)	Needs to be identified*	Linda Dykema	
Communications	Needs to be identified*	Geralyn L/Tim B	- Develop plan - Provide provider education - Provide public education - Provide risk education - Send resources to Flint

Scott, Robert L. (DHHS)

From: Marc Edwards <edwardsm@vt.edu>
Sent: Monday, September 21, 2015 1:20 PM
To: Scott, Robert L. (DCH)
Subject: RE: New DCH-1294, time-sensitive

I am not sure how we can proceed. The Age in months would be fine.

But is it true that providing zip code level analysis, if you combine 48503 and 48504 into a "high risk" Flint area (50000+ residents), and the rest into a "low risk" Flint area, is by definition identified?

In that case, do I need to do an IRB, with my institution, to obtain data from you identified at the zip code level, and then get approval for that? Data would only be handled by me on my computer which is password protected.

If I get our IRB approval for my study with only zip code identified, are you then allowed to share that data (with zip code identified) with me?

Ultimately, zip code data will be combined into EBL% within that zip code, and there is no intention to look at individuals except by age in months.

I am not sure how to proceed.

Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Tuesday, September 15, 2015 5:10 PM
To: Marc Edwards
Subject: RE: New DCH-1294, time-sensitive

I can certainly provide age in years instead of date of birth, although either one would be acceptable according to this link I found:

http://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/limited_data_set.html

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Tuesday, September 15, 2015 4:58 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Can you tell me how I can do a limited dataset? Can I just have the age in years, for example?

Thanks so much!

Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Tuesday, September 15, 2015 9:21 AM
To: Marc Edwards
Subject: FW: New DCH-1294, time-sensitive

Marc,

Please see Colin's (Legal Affairs) comments below. I apologize for not passing it along yesterday—the day got away from me. I clearly have a lot to learn—I made changes to your document thinking it was a slam-dunk as de-identified, but was wrong, as indicated below.

Please make changes to your DCH-1294 as directed by Colin's comments, and re-submit to me, still no signature.

Thanks,
Bob

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 2:08 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Cc: Horste, Ian (DCH) <Horstel@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert,

Here are my comments regarding this DUA. Please feel free to give me a call if you have any questions. As I indicate below, we also need to see about whether our IRB needs to be involved.

1. I want to know more about the study that is being recreated in item 1. The attached protocol seems to discuss more about the study of the water samples, not the blood lead data. Saying that the researcher wants to verify the claim of MDEQ is not sufficient. It does not have to be a great deal longer, but it should explain what the intended use of the blood lead data is.

It is also important to know exactly how it will be used for research in order to justify the release not just under HIPAA, but also under R 325.9086 pertaining to the confidentiality of blood lead test reports. It must be for the "If necessary for the purpose of research designed to develop or contribute to generalizable knowledge, with documented approval by the department's institutional review board." R 325.9086(2)(e). I am not sure how Ian would handle this, given the language in the rule that seems to require IRB approval.

2. Tying in with 1. above, telling us that the analysis will be similar to some other study is insufficient. This section should tell us how the data will be used and disclosed, how many people (research team) might have access, what formats it might be used in and other similar information. The attached research protocol, as noted above, does not get into sufficient detail regarding exactly how our blood lead data will be used and how its use will be restricted.

I also need to know more about how the data will be secured on their end, how it will be handled, by who, and what will be done with it when it is no longer needed for their study.

3. The researcher indicates this data will be deidentified, but then goes on to ask for a number of identifiers that make the data identifiable, including county, city, and birth date of the child. In order for data to be deidentified (short of the statistical analysis method which would have to be documented and shown to us), it must not contain any geographic subdivision smaller than state. 45 CFR 164.414(b)(2)(i)(B).

Additionally, all elements of dates related to the individual must not be included, which includes birth date. 45 CFR 164.414(b)(2)(i)(C). Therefore, the researcher must follow protocols for identifiable data, which may include requesting a waiver of informed consent from the IRB.

The researcher could possibly obtain the data requested as a limited data set without a waiver I believe (though we still would want to run it by the IRB). If this is the case, item 3.b. should be changed to "Limited Data Set."

Colin Boes, JD
Privacy Specialist
Office of Legal Affairs & FOIA
Michigan Department of Health & Human Services
201 Townsend St.
Lansing, Michigan 48933
(517) 335-8558 – T (517) 241-1200 - F

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:44 PM
To: Boes, Colin (DCH)
Subject: RE: New DCH-1294, time-sensitive

Thanks. I was told by a colleague of mine that Ian is expected back on Monday (I hope she was right).

I think the researcher is hoping for a turn-around with a week or so, but I'm sure he knows he can't make (and hasn't made) demands. I'll check with him about an IRB.

From: Boes, Colin (DCH)
Sent: Friday, September 11, 2015 1:33 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: New DCH-1294, time-sensitive

Robert, thank you for letting me know about the time-sensitivity. I will do my best to get this turned around as soon as I can. Since this involves research you may wish to send it the IRB as well and let them know about the urgency. How soon do you think they were hoping to get it back? A few weeks? Shorter? I ask because our IRB director Ian is out of the office until at least next week (I cannot remember exactly how long he is out).

Colin Boes, JD
Privacy Specialist
Office of Legal Affairs & FOIA
Michigan Department of Health & Human Services
201 Townsend St.
Lansing, Michigan 48933
(517) 335-8558 – T (517) 241-1200 - F

From: Scott, Robert L. (DCH)
Sent: Friday, September 11, 2015 1:26 PM
To: Boes, Colin (DCH)
Subject: New DCH-1294, time-sensitive

Colin,

Please see attached DUA and related proposal. I'm asking for a reasonably-quick turn-around on this request for de-identified data, if possible given your schedule. I've pasted Professor Edwards' comments below:

"Yes, I think there is clearly some urgency to the situation.

MDEQ has publicly stated that your blood lead records, are showing that there is no public health concern for residents in Flint.

The levels of lead in Flint water, that we are finding in our water sampling, are certainly in a range that can cause childhood lead poisoning.

Indeed, one child has already, likely been lead poisoned from exposure to high lead in water.

I think the fact that you already have other teams working on these records, indicates a high level of interest, and urgency.

Congressional interest in the safety of the water is also very high, and this will be an important issue in deciding options for treating the water, in the weeks and months ahead."

Thanks,
Bob

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

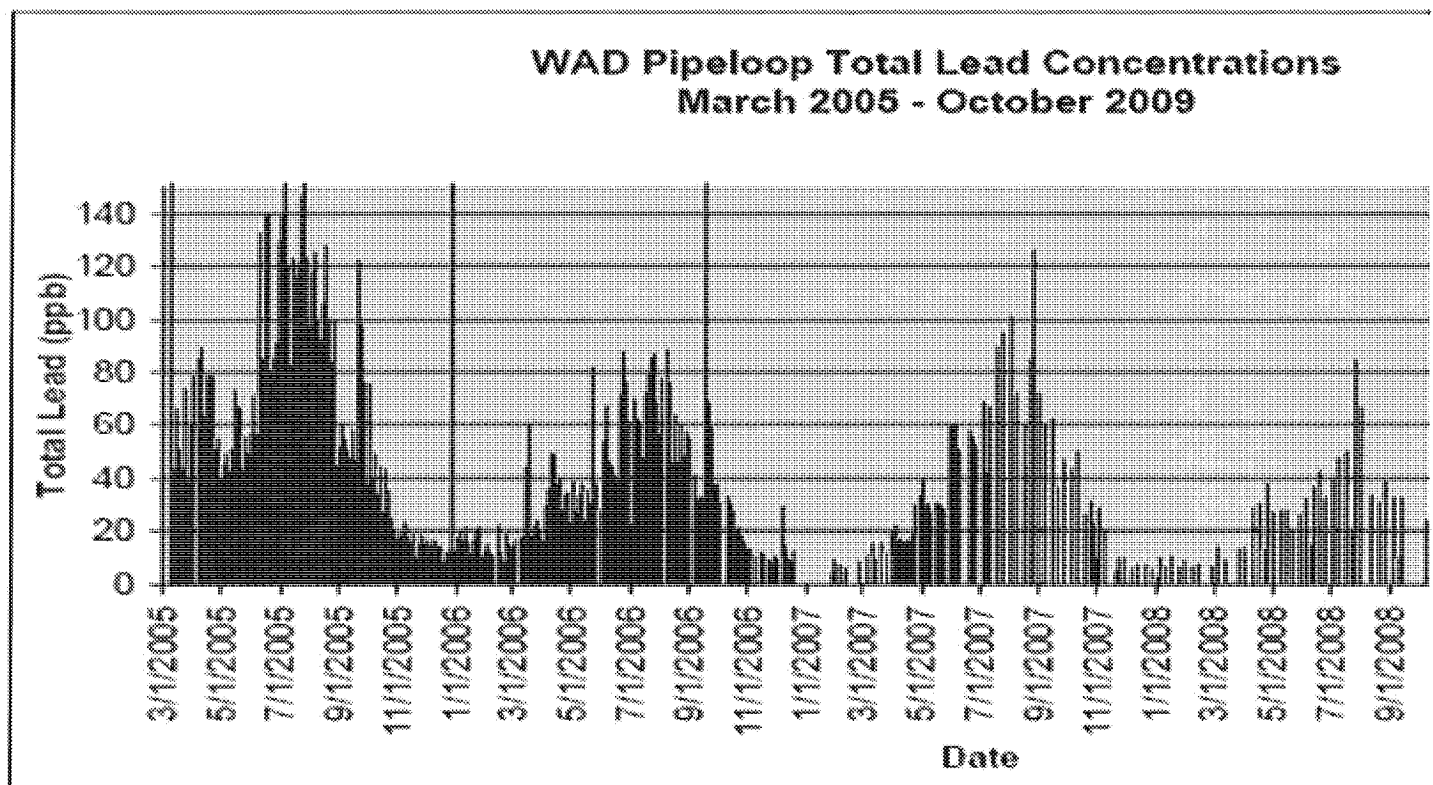
Scott, Robert L. (DHHS)

From: Marc Edwards <edwardsm@vt.edu>
Sent: Friday, September 25, 2015 10:08 PM
To: Scott, Robert L. (DCH)
Subject: lead in water seasonal

These results are from lead pipe loops run at the Washington Aqueduct in Triplicate....you get the idea.
The correlation with temperature in that system was something like $R^2 = 0.7$ or so.

There are also peer reviewed papers showing that blood lead in summer peaks due to elevated water lead.
Water lead does not have to be constant. This is well known.

Marc



Scott, Robert L. (DHHS)

From: Marc Edwards <edwardsm@vt.edu>
Sent: Friday, September 25, 2015 1:12 PM
To: 'Mona Hanna-Attisha'; Scott, Robert L. (DCH); 'Jenny LaChance'
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Mona,

When you get the data let me know. Since you are involved and have apparently requested the data already (independently), I will not be bothering Robert further.

However, I will be speaking out, about the unethical behavior of the state in not sharing the data to date, and their abusing of power to discredit the work you have done.

The second they give you the data I will stop speaking out.

Robert, I apologize to you because I know you did not have anything to do with it, but what is happening here is just wrong.

Best Regards,

Marc

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Friday, September 25, 2015 1:00 PM
To: 'Mona Hanna-Attisha'; 'Scott, Robert L. (DCH)'; 'Jenny LaChance'
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

I understand that, and I appreciate what you are doing.

I also hope you can understand my frustration, at seeing this data given to reporters in an relatively unprocessed and unscientific format, used to support a claim that there is not a problem with lead in water in Flint.

And worst of all, seeing it used to "refute" the sound science that Mona did with her in-house data. I know you did not have anything to do with that, but I strongly feel that what is happening is unethical.

I hope you send my message to whoever is abusing the data (and the public trust, and the science method) in this way.

I will be calling the state out on this abuse, as long as it continues. I stand by my statements this is third rate and unscientific science that is being circulated by the state, and your department should have expedited Mona's requests to get access to the data. I am probably going to step aside and let her handle it from here, and as soon as you get her the data I will stop speaking out. She has proven herself to be a capable researcher.

You should also tell the team that is analyzing the data, that lead in water often peaks in the summer months, and declines in the winter months. It is clear from their one pager that they do not know the first thing about lead in water.

Marc

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Friday, September 25, 2015 12:51 PM
To: 'Scott, Robert L. (DCH)'; Marc Edwards; Jenny LaChance
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Thanks Bob. We greatly appreciate all your assistance and your hard work!

It's interesting to note that the number of children tested in July and August of 2015 is so small as compared to the same months in previous years? Do you think those numbers capture all the tests that were done – is there a lag time in reporting to your system?

Thanks! Mona

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Friday, September 25, 2015 12:44 PM
To: Marc Edwards
Cc: Mona Hanna-Attisha; Peeler, Nancy (DCH); Minicuci, Angela (DCH)
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Marc,

As you well know, the data you and Dr. Hanna-Attisha have requested are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public.

I worked with you earlier this month to get data to you relatively quickly, but we did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away. I returned on Wednesday and corresponded that day with Dr. Hanna-Attisha, providing her with the forms she'll need for her request.

Regarding your email from Monday, I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, will adjust it to say "limited data set" instead of "de-identified," and will re-submit it to our Legal office. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of the Waiver Request when we talked earlier this month.) Send those documents to me, and I'll pass them on to our IRB contact. I don't know whether you'll need to go through an IRB review with your institution.

In short, both your request and Dr. Hanna-Attisha's are in process in accordance with departmental policies.

I've attached a PDF that includes the numbers behind the graphs you referred to, and I'm CC'ing Dr. Hanna-Attisha so that she has it as well.

Please keep in mind that I work for a very small program responsible for processing several thousand blood lead results every week--in order to get them out to the professionals working directly with children and families, which is the primary purpose and highest priority of our program.

Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Dear Robert,

I just spoke to this young researcher at Hurley, and apparently, she has been unable to get access to the state blood lead records.

I have to say, it is very disturbing that the state keeps issuing these blood lead reports and statements in their press releases, and refuses to share the data backing them up with outside researchers.

Even worse, state reps are running around claiming that these reports are proof that Flint water is safe to drink.

Can you tell me why it is so difficult to get this data, and why your agency is raising so many obstacles to sharing it with everyone who asks? I note that I have been asking to see your data since MDEQ first sent it to reporters back in August, and I count 10 e-mails that I sent responding to all your questions. As of yet, you have given me nothing in response. Yet you have been sending reporters one report after another. It seems your agency is more interested in public relations than sound science.

In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 9:35 AM
To: Minicuci, Angela (DCH); Eisner, Jennifer (DCH)
Cc: Peeler, Nancy (DCH)
Subject: question on email response regarding Flint blood lead data
Attachments: Flint Testing and EBLLs_updated 092315_with notes.pdf; HIPAA Waiver Request Template.doc; DCH-1277 IRB Initial Review Application.doc

Angela or Jennifer,

Please see Dr. Edwards email below, and my draft response to him. I'm not very happy with him right now, but tried to respond appropriately. Given the sensitive nature of the situation, I'm checking with you first. Nancy is on annual leave, but I've CC'd her here.

Is it OK to send this? Please feel free to make changes as appropriate. I'm also asking if it's OK now to share the attached PDF with Dr. Edwards and Dr. Hanna-Attisha.

Thanks,
 Bob

Marc,

As you well know, the data you and Dr. Hanna-Attisha are requesting are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public. In addition, my Department has policies on how to determine what can be shared.

I worked with you earlier this month to get data to you relatively quickly, but did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away, and I apologize for not informing you. Unfortunately we are a very small program, and there's no one else here to process your request—or Dr. Hanna-Attisha's.

Since I returned on Wednesday, my time has been largely taken up with my Department's response to the current situation in Flint. I did manage to correspond to Dr. Hanna-Attisha, and provided her with the forms she'll need for her request. I hope to submit her request to our Legal office and to our IRB contact today.

Sorry I haven't responded to your email from Monday—as I mentioned above, I was away, and then have been juggling many tasks since I returned. I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, and will adjust it to say "limited data set" instead of "de-identified." I'll re-submit your DUA to Legal today. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of that when we talked earlier this month.) I don't know whether you'll need to go through an IRB review with your institution.

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Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

From: Marc Edwards [mailto:edwardsm@vt.edu]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
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In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

Scott, Robert L. (DHHS)

From: Peeler, Nancy (DCH)
Sent: Friday, September 25, 2015 9:53 AM
To: Scott, Robert L. (DCH)
Cc: Minicuci, Angela (DCH); Eisner, Jennifer (DCH)
Subject: Re: question on email response regarding Flint blood lead data

Bob, I appreciate your efforts to work on this email. I think we can apologize less, and just concisely lay out the steps that have been taken, and need to be taken (which you have). Angela and Jennifer, if you have input that can help shape this, I also would appreciate that help.

Nancy

Sent from my iPad

On Sep 25, 2015, at 9:34 AM, Scott, Robert L. (DCH) <ScottR9@michigan.gov> wrote:

Angela or Jennifer,

Please see Dr. Edwards email below, and my draft response to him. I'm not very happy with him right now, but tried to respond appropriately. Given the sensitive nature of the situation, I'm checking with you first. Nancy is on annual leave, but I've CC'd her here.

Is it OK to send this? Please feel free to make changes as appropriate. I'm also asking if it's OK now to share the attached PDF with Dr. Edwards and Dr. Hanna-Attisha.

Thanks,
Bob

Marc,

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I worked with you earlier this month to get data to you relatively quickly, but did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away, and I apologize for not informing you. Unfortunately we are a very small program, and there's no one else here to process your request—or Dr. Hanna-Attisha's.

Since I returned on Wednesday, my time has been largely taken up with my Department's response to the current situation in Flint. I did manage to correspond to Dr. Hanna-Attisha, and provided her with the forms she'll need for her request. I hope to submit her request to our Legal office and to our IRB contact today.

Sorry I haven't responded to your email from Monday—as I mentioned above, I was away, and then have been juggling many tasks since I returned. I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, and will adjust it to say "limited data set" instead of "de-identified." I'll re-submit your DUA to Legal today. You will need to submit an MDHHS IRB review application (attached) because this is considered research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of that when we talked earlier this month.) I don't know whether you'll need to go through an IRB review with your institution.

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Bob

Robert L. Scott
 Childhood Lead Poisoning Prevention Program
 Michigan Department of Health & Human Services
 (517) 335-8178
 fax (517) 335-8509

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

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Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

<Print Testing and EBLs_updated 092315_with notes.pdf>

<HIPAA Waiver Request Template.doc>

<DOH4277 IRB Initial Review Application.doc>

Scott, Robert L. (DHHS)

From: Peeler, Nancy (DCH)
Sent: Friday, September 25, 2015 10:37 AM
To: Scott, Robert L. (DCH)
Subject: Re: question on email response regarding Flint blood lead data

I'm sitting in Zoe's quantum mechanics class, no clue what these differential equations are telling me, but I am stewing a bit about this situation. I want to say that you always do a great job, and are responsive to all data requests, and advocate to help researchers get whatever paperwork completed and turned in. That's why this feels so inappropriate to me - this isn't your fault, thus my earlier comment about apologizing less. And having said that, it probably wasn't a really helpful comment toward revising the response.

The email you received could be read as an intent to escalate and spin things, and I don't think you need to get caught up in that. A calm, fact-based response is very appropriate.

I think your first paragraph is good, but I would remove the last sentence, as I'm not sure what policies you are referencing beyond state and federal law -- and, I think the state and federal law carry enough weight that our departmental policies probably don't change much of anything about the process.

For paragraphs 2 and 3 I think I would just say state the facts, which is that both requests are in process in accordance with departmental policies - because they are. You really don't need to apologize for taking vacation, and I consider anybody's vacation time to be a normal part of doing business - none of us are expected to be at our desks every day, and there is no way to predict what might come up when we are planning to be away.

In your 4th paragraph, it looks like he is changing his data request? I appreciate your generosity in taking on responsibility to do his work for him (editing his paperwork) - your option, whether you want to do that, or request that he re-do it. I would outline the steps, clarify that you have confirmed the process which revealed the extra step, and let him know you'll watch for his response.

Finally, I might close with the piece about a small program, responsible for processing a high number of results every day or week (you sent me a number last week) in order to get them out to the professionals working directly with children and families, which IS the purpose and highest priority of our program.

I hope some of this is helpful and not too late - hope the rest of the day goes better. Thank you for all you do!

Sent from my iPad

On Sep 25, 2015, at 9:34 AM, Scott, Robert L. (DCH) <ScottR9@michigan.gov> wrote:

Angela or Jennifer,

Please see Dr. Edwards email below, and my draft response to him. I'm not very happy with him right now, but tried to respond appropriately. Given the sensitive nature of the situation, I'm checking with you first. Nancy is on annual leave, but I've CC'd her here.

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Bob

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 24, 2015 8:14 PM

To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

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Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.

<Flint Testing and EBLLs_updated 092315_with notes.pdf>

<HIPAA Waiver Request Template.doc>

<DCH-1277 IRB Initial Review Application.doc>

Scott, Robert L. (DHHS)

From: Scott, Robert L. (DCH)
Sent: Friday, September 25, 2015 1:02 PM
To: 'Mona Hanna-Attisha'; Marc Edwards; Jenny LaChance
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Mona,

There's generally a lag of about two weeks from the date of the test to its being fully processed in our system. A few results take longer, for a variety of reasons. 99% of all results through August should be reflected in those numbers. Not sure why the last few months were so low.

Thanks,
 Bob

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Friday, September 25, 2015 12:51 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>; Marc Edwards <edwardsm@vt.edu>; Jenny LaChance <JLachan1@hurleymc.com>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Thanks Bob. We greatly appreciate all your assistance and your hard work!

It's interesting to note that the number of children tested in July and August of 2015 is so small as compared to the same months in previous years? Do you think those numbers capture all the tests that were done – is there a lag time in reporting to your system?

Thanks! Mona

From: Scott, Robert L. (DCH) [mailto:ScottR9@michigan.gov]
Sent: Friday, September 25, 2015 12:44 PM
To: Marc Edwards
Cc: Mona Hanna-Attisha; Peeler, Nancy (DCH); Minicuci, Angela (DCH)
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Marc,

As you well know, the data you and Dr. Hanna-Attisha have requested are derived from personal health data, which of course is confidential. There are state and federal laws governing what can be shared, and how, with researchers or the public.

I worked with you earlier this month to get data to you relatively quickly, but we did not manage to complete the process before I went on annual leave for several days. I neglected to inform you that I'd be away. I returned on Wednesday and corresponded that day with Dr. Hanna-Attisha, providing her with the forms she'll need for her request.

Regarding your email from Monday, I think you'll be able to get approval for data with zip code identified. I'll edit your data use agreement accordingly, will adjust it to say "limited data set" instead of "de-identified," and will re-submit it to our Legal office. You will need to submit an MDHHS IRB review application (attached) because this is considered

research. You should also submit a "HIPAA Waiver Request" (attached). (I wasn't aware of the Waiver Request when we talked earlier this month.) Send those documents to me, and I'll pass them on to our IRB contact. I don't know whether you'll need to go through an IRB review with your institution.

In short, both your request and Dr. Hanna-Attisha's are in process in accordance with departmental policies.

I've attached a PDF that includes the numbers behind the graphs you referred to, and I'm CC'ing Dr. Hanna-Attisha so that she has it as well.

Please keep in mind that I work for a very small program responsible for processing several thousand blood lead results every week--in order to get them out to the professionals working directly with children and families, which is the primary purpose and highest priority of our program.

Bob

Robert L. Scott
Childhood Lead Poisoning Prevention Program
Michigan Department of Health & Human Services
(517) 335-8178
fax (517) 335-8509

From: Marc Edwards [<mailto:edwardsm@vt.edu>]
Sent: Thursday, September 24, 2015 8:14 PM
To: Scott, Robert L. (DCH) <ScottR9@michigan.gov>
Subject: RE: Automatic reply: New DCH-1294, time-sensitive

Dear Robert,

I just spoke to this young researcher at Hurley, and apparently, she has been unable to get access to the state blood lead records.

I have to say, it is very disturbing that the state keeps issuing these blood lead reports and statements in their press releases, and refuses to share the data backing them up with outside researchers.

Even worse, state reps are running around claiming that these reports are proof that Flint water is safe to drink.

Can you tell me why it is so difficult to get this data, and why your agency is raising so many obstacles to sharing it with everyone who asks? I note that I have been asking to see your data since MDEQ first sent it to reporters back in August, and I count 10 e-mails that I sent responding to all your questions. As of yet, you have given me nothing in response. Yet you have been sending reporters one report after another. It seems your agency is more interested in public relations than sound science.

In the meantime, can I at least be given the numbers of EBL cases and number of tests each month, that are the basis for the latest graph your agency is sending to the press...or is that top secret as well?

Marc

From: Scott, Robert L. (DCH) [<mailto:ScottR9@michigan.gov>]
Sent: Monday, September 21, 2015 1:21 PM
To: Marc Edwards
Subject: Automatic reply: New DCH-1294, time-sensitive

I'll be out of the office until Wednesday, Sept 23. I'll respond to your message when I return.