

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850



State Demonstrations Group

July 19, 2021

Kate Massey
Director
State of Michigan, Medical Services Administration
400 South Pine Street
Lansing, MI 48913

Dear Ms. Massey:

The Centers for Medicare & Medicaid Services (CMS) completed its review of the Interim Evaluation Report, which is required by Special Terms and Conditions (STCs) of Michigan's section 1115 demonstration, "Flint Michigan Section 1115 Demonstration" (Project No: 11-W-00302/5), specifically STC #58 "Interim Evaluation Report." This report covers the demonstration period from May 2016 to April 2019. CMS determined that the evaluation report, which was submitted on April 30, 2020, and most recently revised on May 20, 2021 is complete and responsive to feedback and therefore approves the state's Interim Evaluation Report evaluation.

In accordance with 42 CFR 431.424 d(2), the approved evaluation design may now be posted to the state's Medicaid website within thirty days. CMS will also post the evaluation report on Medicaid.gov.

The Interim Evaluation Report identified positive trends in health outcome measures, such as improvements in developmental screenings for children and self-reported health. However, data also show that less than 40 percent of the eligible population enrolled as of 2019. Additionally, the report appropriately identifies several methodological limitations. The report did not address several research questions in the CMS-approved evaluation design, due to difficulty identifying an appropriate comparison group, difficulty obtaining the necessary data, and the lack of rigorous statistical analyses. Thus, the effects of the demonstration are inconclusive based on the results presented in the interim evaluation report.

We look forward to collaborating with the state on the Final Evaluation Report, which we expect will address these limitations by comparing the demonstration population to a comparison group and using more rigorous statistical methodologies, such as regression analysis to control for confounding factors. In so doing, the state will be better able to assess the causal impact of the demonstration, rather than reporting descriptive trends over time.

We appreciate the state’s commitment to refining the Interim Evaluation Report and efficiently addressing CMS’s feedback. We look forward to continuing our partnership on the Flint Section 1115 Demonstration and in particular to ensure the Final Evaluation Report is an informative analysis of the impacts of this important demonstration. If you have any questions, please contact your CMS demonstration team.

Sincerely,

Danielle Daly
-S

Digitally signed by
Danielle Daly -S
Date: 2021.07.19
11:50:30 -04'00'

**Andrea J.
Casart -S**

Digitally signed by Andrea
J. Casart -S
Date: 2021.07.19
12:30:33 -04'00'

Danielle Daly
Director
Division of Demonstration
Monitoring and Evaluation

Andrea Casart
Director
Division of Eligibility and
Coverage Demonstrations

cc: Keri Toback, State Monitoring Lead, CMS Medicaid and CHIP Operations Group



Flint, Michigan Section 1115 Demonstration

#11W 00302/5

2018/2019 Cumulative Interim Report

Submitted 1/15/20

REVISED NOVEMBER 9, 2020 and MAY 19, 2021



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Executive Summary

In April 2014, Flint, Michigan experienced a public health crisis related to its water supply. The City of Flint switched the water sources from Lake Huron and Detroit River to the Flint River to reduce costs. This switch and its water treatment process caused lead and other toxins to leach from pipes that delivered water into homes. As a result, many residents experienced serious health problems. Chief among them was lead exposure in pregnant women and children. Health providers discovered that Flint children's blood lead levels (BLL) increased significantly from 2.4% to 4.9% after the water source change.¹ Those neighborhoods with aging lead pipes and infrastructure experienced a 6% increase in lead levels in the drinking water.²

Lead is a neurotoxin and high BLLs can affect the developing brain and neural systems. Lead exposure in utero and young children has the potential to cause serious physical and developmental delays. Most notably, these neurodevelopmental effects can impact intelligence, behavior, and a healthy life trajectory. Likewise, in unborn children lead crosses the placenta as a toxin and may cause miscarriage, low-birth weight, and affect major organs. These effects are difficult to ameliorate and often sustain into adulthood.

In 2016, the federal government declared the Flint Water Crisis an emergency and leveraged funds to assist residents facing immediate effects of the contaminated water. To address the sustained public health crisis directly, the Centers for Medicare and Medicaid Services (CMS) administered funds via the Michigan Department of Health and Human Services (MDHHS) to expand eligibility and access to healthcare for pregnant women and children under 21 years. The Flint Medicaid Expansion (FME) **was approved March 3, 2016** and enrollment commenced on May 9, 2016, **approximately** two years after the water switch date of April 25, 2014. This Medicaid Section 1115 Waiver expanded eligibility and services in two ways: 1) increased the income eligibility from a maximum of 212% FPL to 400% FPL, and 2) included Targeted Case Management of specialized services.

MDHHS engaged Michigan State University's Institute for Health Policy (IHP) to evaluate the expansion of Medicaid services in four domains: 1) access to care; 2) access to targeted case management; 3) improved health outcomes; and 4) lead hazard investigation. The four domains offer specific hypotheses to guide the evaluation. The evaluation plan was approved August 8, 2017 **and contracting to support the work was effective January 2018**. In this cumulative interim report, **completed** evaluation activities and progress from 1/1/2018 to 12/31/19 are described. **Activities in process as of this revision date (November 2020) are identified where applicable and anticipated timelines for completion described. The full scope of 2020 activities will be available in a forthcoming Evaluation Annual Report with an anticipated submission date of 2/28/21.**



The anchor point selected for evaluation activities was May 1, 2016 to most closely coincide with the initial waiver enrollment date of May 9, 2016. Due to the two-year gap between the water switch and waiver enrollment, three periods are considered:

Table 1: Evaluation Timeframe Reference

Timeframe Code	Timeframe Description
T1	baseline year prior to the water switch (May 1, 2013 – April 30, 2014)
T2	post water switch, FME not implemented (May 1, 2014 – April 30, 2016)
T3	post water switch, FME implemented (May 1, 2016 – present)

Predominant evaluation activities carried out during calendar year 2018 included acquisition of data, data preparation, securing resources to implement the evaluation, engaging key stakeholders, and preliminary analyses. Activities during calendar year 2019 included expansion of available results as well as implementation of enrollee and provider surveys. **While evaluation work during calendar year 2020 was complicated by the coronavirus pandemic and associated government stay-home orders, waves 2 and 3 of the enrollee survey and TCM Key Informant Interviews were still conducted. Additional utilization data through 4/30/2020 was acquired through the MDHHS data warehouse. The analyses of these additional data elements will be described in the forthcoming 2020 Evaluation Annual Report.**

The results describe enrollment and utilization data acquired from the MDHHS Health Services Data Warehouse. Reported utilization **is expanded from 5/1/2013 through 4/30/2019** due to allowances for claims processing. Data sources targeted for the upcoming **2020 evaluation year activity** include medical record data from the Genesee Health System and public data sources such as *MI Schools* and *Lead Safe Home*.

Evaluation of administrative data sets along with enrollee survey responses suggest that the waiver has had a degree of success in meeting the overarching goal **to identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards**. With respect to the four domains referenced in the waiver application, currently available data suggest positive impacts have been realized in some of the measures for three of the domains having data available. The lead hazard investigation domain has not yet been evaluated and no interim opinion can be rendered. **Additional data to support all four domains has been accrued during 2020. These data are being processed and analyzed at this time and will be presented in the forthcoming 2020 Evaluation Annual Report to be submitted by February 28, 2021.**

The first domain, Access to Care, has been supported by the information provided directly by enrollees **through the survey process**. Most respondents documented the waiver made it easier for them to access care and services. Based on administrative health care data, several



measures suggested increased utilization since the water switch (e.g. developmental or behavioral screening, retesting of children having elevated BLL and lead testing in pregnant women). ***During 2020, administrative data sets have been extended to include dates of service through 4/30/2020. Further, Wave 2 of the enrollee survey was completed and a comparison between Wave 1 and Wave 2 responses will be available in the upcoming 2020 Evaluation Annual Report.***

The second domain, Access to TCM, has been shown in preliminary analyses to have limited impact predominantly due to the low uptake and participation. Both administrative and TCM Data provided by the TCM Provider organization show rates less than 5% while survey respondents do not report participation in excess of 10%. Despite the lower than anticipated penetration, those who have participated report satisfaction with the benefit. ***During calendar year 2020, a follow-up TCM Provider Key Informant Interview was conducted to augment the enrollee survey data. These results will be incorporated in the 2020 Evaluation Annual Report.***

The third domain, Improved Health Outcomes, has been predominantly supported by the data collected during the beneficiary survey as well. Most respondents report health status rankings as good, very good or excellent. However, a discrepancy is observed between physical health status and behavioral/emotional health status with behavioral health status being rated significantly worse. Responding beneficiaries further report increased confidence and resources to manage chronic conditions since enrollment. ***The addition of the Wave 2 enrollee survey responses will provide longitudinal data to determine the degree to which improved health outcomes are reported by enrollees. Additional reports that provide comparison information for selected health outcomes have been identified. These include the University of Wisconsin's County Health Rankings and the Behavioral Risk Factor Surveillance Survey. The reports vary but provide county or regional estimates. Historical data is available to a varying degree. The evaluation team is further investigating the Michigan Kids Count reporting for the ability to refine to county level.***

Preliminary analyses on the last domain, Lead Hazard Investigation remain in progress and are unavailable currently. External community reports indicate positive trends in water lead values decreasing and number of environmental investigations completed through 2017. ***The Flint Lead Free subgroup of the CDC-funded Flint Registry is collecting data on the status of environmental lead exposure and identifying resources. The evaluation team is collaborating with the Flint Registry and has access to their published reporting.***

The full impact of the approved Flint Waiver cannot yet be assessed until the completion of the waiver evaluation period originally scheduled through April 30, 2021. Early results suggest the waiver has provided a level of success in achieving the state's overarching goal. An unanticipated positive finding arising from the evaluation activities was the interest and participation in web-based surveys by enrollees.

General Background Information

In 2016, the Michigan Department of Health and Human Services (MDHHS) received a 1115 waiver from the Centers for Medicare and Medicaid Services (CMS) to expand Medicaid coverage and benefits to individuals affected by the Flint Water Crisis.

The Flint Water Crisis occurred when the city's water source was changed in April 2014 to the Flint River. This water did not receive appropriate treatment and subsequently caused lead to leach from pipes, increasing the incidence of elevated lead levels in tap water and in children's blood. Over 100,000 residents were affected and among those were approximately 25,000 infants and children.³ In January 2016, President Obama declared an emergency in Flint, leveraging federal aid to support state and local response efforts.

The Flint Medicaid Expansion (FME) Waiver provided and continues to provide expansion of health services to address potential health risks and diseases possibly incurred during exposure to lead during the Flint Water Crisis. As of **November 1, 2020**, lead exposure is still a threat since all the water supply lines have not yet been replaced. Because lead is a known neurotoxin,² MDHHS applied for the waiver to expand Medicaid coverage to individuals who may have been exposed, but not eligible for Medicaid due to income limitations. Given the known adverse impact on neurological development,⁵ the target populations identified in the application included infants and children as well as pregnant women.

The overarching goal of the MDHHS waiver application was to *"identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards."* The demonstration waiver expanded eligibility of all Medicaid benefits for low-income children (up to age 21 including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water region from 4/25/2014 through the date when the water is deemed safe. As of **November 1, 2020**, the water has not yet been deemed safe although lead levels are below national thresholds. The specific eligibility modifications included:

- Increase income threshold to offer coverage to children in households with incomes from 212% federal poverty level (FPL) up to and including 400% FPL.
- Increase income threshold to offer coverage to pregnant women in households with incomes from 195% FPL up to and including 400% FPL.
- Eliminate cost sharing and Medicaid premiums for eligible children and pregnant women served by the Flint water system.
- Permit eligible children and pregnant women above the 400% FPL and served by the Flint water system to buy into Medicaid benefits by paying premiums.

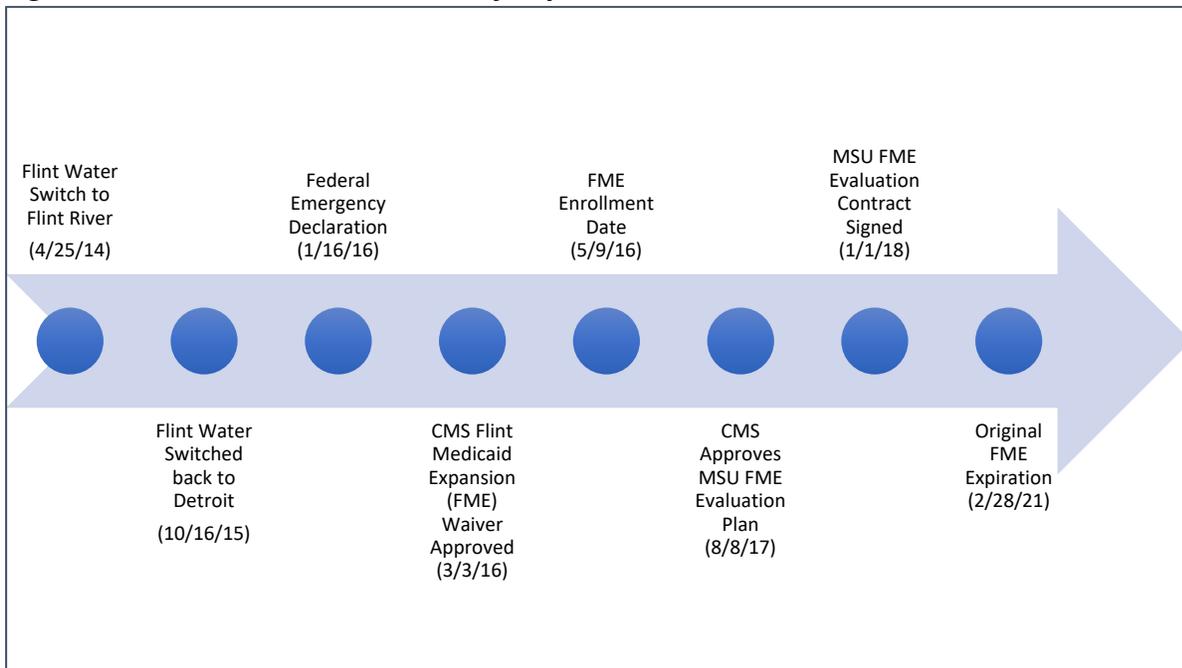
The demonstration also added a Targeted Case Management (TCM) benefit to all low-income children (up to age 21 including children born to eligible pregnant women) and pregnant women (through two months post-delivery) served by the Flint water system as of 4/25/2014. The activities included in the TCM benefit were to:

- Assist enrolled eligible children and pregnant women served by the Flint water system to gain access to needed medical, social, educational, and other service(s).

The 1115 Waiver entitled the *Flint, Michigan Section 1115 Demonstration #11W 00302/5* was **approved March 3, 2016 and enrollment commenced on May 9, 2016, approximately two years after the water switch date of April 25, 2014**. A condition of this waiver authorization was the requirement for an independent evaluation. Michigan State University’s Institute for Health Policy (IHP) collaborated with CMS on the evaluation goals and activities. **The evaluation plan was approved August 8, 2017 and contracting with MDHHS to support the work was effective January 1, 2018**.

Multiple key dates were considered to anchor the evaluation work including water switch date, waiver approval date, waiver enrollment date and contracting date. Figure 1 provides a timeline of the key dates associated with the Flint Water Crisis that were under consideration.

Figure 1: Flint Water Crisis Timeline of Key Events





The original anchor point identified for evaluation activities was April 1, 2016. Shortly after the start of the evaluation work, the anchor point was revised to May 1, 2016 to coincide with the initial waiver enrollment date of May 9, 2016. This rationale for this selection was that the influence of the waiver activity would be most closely accounted for with a twelve-month reporting cycle running from May through April. Due to the two-year gap between the water switch and waiver enrollment, three main timeframes are considered:

Table 1: Evaluation Timeframe Reference

Timeframe Code	Timeframe Description
T1	baseline year prior to the water switch (May 1, 2013 – April 30, 2014)
T2	post water switch, FME not implemented (May 1, 2014 – April 30, 2016)
T3	post water switch, FME implemented (May 1, 2016 – present)

The evaluation team includes faculty and staff from IHP as well as faculty from the College of Human Medicine’s Department of Epidemiology and Biostatistics, Division of Public Health, and the Office of Research. Additionally, faculty and staff from the College of Social Science, Office for Survey Research are members of the evaluation team. The team includes:

- Hong Su An, PhD; Institute for Health Policy, College of Human Medicine
- Karen Clark, BA; Office for Survey Research, Institute for Public Policy & Social Research
- Debra Darling, BSN, RN, CCP; Institute for Health Policy, College of Human Medicine
- Julie DuPuis, MPA; Institute for Health Policy, College of Human Medicine
- Sabrina Ford, PhD; Institute for Health Policy, College of Human Medicine
- Mona Hanna-Attisha, MD, MPH, FAAP; Department of Pediatrics, College of Human Medicine and Hurley Medical Center
- Joan Ilardo, PhD, LMSW; Office of Research, College of Human Medicine
- Nicole Jones, MS, PhD, Division of Public Health, College of Human Medicine
- Christine Karl, RN, BA; Institute for Health Policy, College of Human Medicine
- Zhehui Luo, PhD; Department of Epidemiology and Biostatistics, College of Human Medicine
- Kathleen Oberst, PhD, RN; Institute for Health Policy, College of Human Medicine
- Debra Rusz, MA; Office for Survey Research, Institute for Public Policy & Social Research;
- Richard Sadler, PhD; Division of Public Health, College of Human Medicine
- Lin Stork, MA; Office for Survey Research, Institute for Public Policy & Social Research



The evaluation findings contained in this report are preliminary and reflect the activities conducted by the evaluation team during calendar years 2018 and 2019. ***The report has been revised as requested by CMS. A subsequent 2020 Evaluation Annual Report extending the results of this report to include activities occurring and results obtained during calendar year 2020 is in process. The 2020 Evaluation Annual Report will be submitted to MDHHS February 28, 2021.***

The ***original*** evaluation timeframe is scheduled through April 2021 based on the original FME end date of 2/28/21. ***Upon reflection of the 12-month reporting cycle (May – April), we believe extending this timing would enhance the ability to incorporate the full five years of the waiver activity. This allows time for claims run-out. A six-month window had been applied for the earlier evaluation work which we propose shortening to four months. MDHHS colleagues have estimated fee-for-service professional claims completeness at 94 percent for the four month timeframe. Because encounter submission from managed care organizations lags behind fee-for-service processed claims, we anticipate having a combined dataset of encounter submissions and fee-for-service claims that represents 90% of complete utilization data at four months by August 31, 2021.***

The evaluation team has also considered the impact of the coronavirus pandemic on health care utilization. Specifically, the State of Michigan issued a “stay-home” order effective March 23, 2020 which was not lifted until April 30, 2020. During this time, non-essential and non-emergent health care services were shut down. The evaluation team is interested in CMS feedback and recommendations regarding coronavirus related adjustments.

We propose to continue the waiver evaluation period so that the full 12-month reporting cycle of administrative data could be obtained August 2021. This would result in the final evaluation report being submitted October 31, 2021.



Evaluation Questions and Hypotheses

The Waiver application referred to four domains in which the expanded Medicaid offerings would support attainment of the overall waiver goal. Described below are Domains, related hypotheses and progress thus far based on the evaluation activities occurring during calendar years 2018 and 2019. **Additional information regarding expected timelines for ongoing activities has been added.** A summary matrix of all measures by domain and steward is available in Appendix 1. A copy of the approved evaluation plan is provided in Appendix 2.

- Domain 1: Access to Care
- Domain 2: Access to Targeted Case Management
- Domain 3: Improved Health Outcomes
- Domain 4: Lead Hazard Investigation

Domain 1: Access to Care

The approved demonstration provided Medicaid coverage and access to health care services to a cohort of individuals who were exposed to the lead contaminated water and potentially at risk for physical and behavioral issues. Data sources to address the hypotheses included data acquired from MDHHS Health Services Data warehouse (enrollment and claims) and the enrollee surveys. Enrollee survey materials and Wave 1 summary are provided in Appendix 3.

Hypothesis 1: “Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure.” Nine (9) sub-hypotheses made up this domain and several of the sub-hypotheses included multiple discrete measures. The overall objectives were to evaluate the use of specified services including: well-child visits, developmental screening assessments, testing and retesting of blood lead levels in pregnant women and children, prenatal and postpartum care, maternal infant health program (MIHP) participation, and improved care and satisfaction.

Children: Access to Care

1. A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.
2. A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures.
3. A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures.



4. A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures.

Pregnant Women: Access to Care

5. Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.
6. A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures.
7. A greater proportion of enrollees will participate with Maternal Infant Home Program services compared to others with similar lead levels.

Improved Care & Satisfaction

8. The majority of enrollees will attest to improved access to health care as a result of the expanded coverage.
9. The majority of enrollees will report improved satisfaction with their ability to access health care as a result of the expanded coverage.

Domain 2: Access to Targeted Case Management

The approved demonstration provided expanded benefits, specifically Targeted Case Management (TCM) to facilitate needed medical, social, educational and other services to a cohort of individuals exposed to the contaminated water and potentially at risk for physical or behavioral health consequences. Required elements of TCM have been described in MDHHS policy and included assessments, planning, linkage, advocacy, coordination, referral, monitoring and follow-up activities. In response to enrollee feedback, TCM was relabeled as Family Supports Coordination (FSC). In the interest of consistency for this report and alignment with the Waiver application and approval materials, the services will continue be referred to as TCM throughout this evaluation document. The potential data sources to test these hypotheses included administrative health care data, TCM provider electronic medical record data, enrollee survey data as well as TCM provider survey data.

Hypothesis 2: *“Enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure.”* Hypothesis 2 encompassed four sub-hypotheses. The first two reflected operational aspects of the new benefit while the remaining two assessed for selected improvement in receipt of specific health care services.

1. Referral source and participation levels with TCM will be tracked among enrollees.
2. All TCM participants will have an annual assessment conducted.



3. A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants.
4. A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants.

In addition to accessible Medicaid data, collaboration and cooperation with Genesee Health System (GHS) related to TCM data was necessary. GHS was the designated provider for TCM services. Additionally, the Greater Flint Health Coalition (GFHC) also provided TCM services and regularly submitted data to GHS for reporting purposes. As of December 2018, a Business Associate Agreement (BAA) was executed between IHP and GHS permitting IHP to obtain and use GHS TCM data contained within the electronic medical record. ***These data were reviewed with the expectation they would provide information*** on TCM referral and screening processes and include available data of those children referred for neuropsychological testing at the Neurodevelopmental Center of Excellence (NCE). ***Unfortunately, the extracts from the electronic health record maintained by GHS were not readily usable for data analyses. The system in use does not allow data pulls only pertaining to TCM specific activities. GHS does maintain enrollee tracking which they have shared with the evaluation team.***

TCM specific questions were included in the enrollee survey previously described and presented in Appendix 3. This was done in order to obtain information regarding self-reported use and satisfaction with the TCM services.

In addition to information documented by the TCM provider organizations as part of an enrollee's medical record, qualitative information was obtained from the professional social workers employed at both organizations as TCM Support Coordinators. The TCM Provider Key Informant Interview summary report and discussion guide documents are available as Appendix 4.

Domain 3: Improved Health Outcomes

Hypothesis 3: *"Enrollees will have improved health outcomes compared to others with similar levels of lead exposure."* Domain 3 included three primary sub-hypotheses to examine: status and rates of age-appropriate immunization, greater birth weights, and improved health status rating during enrollment in relation to a comparison group. These primary sub-hypotheses were selected for the ability to report on them using administrative health care data which was already available to the evaluation team. The evaluation activities also included plans for enrollee surveys which were identified as the data source for the health outcome questions.

There were three provisional sub-hypotheses that were descriptive of neurocognitive, behavioral, and educational outcomes of eligible children. These outcomes were deemed



provisional due to several concerns. The first was concern regarding the inclusion of children enrolled in the Serious Emotional Disturbance (SED) waiver as an appropriate comparison group. Next, access to the education data necessary for evaluation are protected by the Family Educational Rights and Privacy Act (FERPA) and concerns regarding the availability of such data to the evaluation team were raised. The State of Michigan's Department of Education (MDE) requested permission from the federal Department of Education to share individual-level data for purposes of the waiver evaluation. The request was denied thus prohibiting the state from sharing these data. The evaluation team thus had to rely on publicly available school system data which was less robust and had no ability to accurately categorize children as a waiver enrollee versus member of a potential comparison group. Within the provisional hypotheses, the specific metrics associated with behavioral and educational outcomes included measuring the proportion of occurrence of severe emotional disturbance and developmental disabilities; the number of children suspended or expelled from school; and the number of children receiving special education services.

After learning of the FERPA denial, questions pertaining to the provisional hypotheses were added to the enrollee survey. The evaluation team also sought out guidance from additional MSU faculty having experience with publicly available MDE summary reports. The evaluation team will explore how these may provide context to findings during the remainder of the evaluation period.

Primary Hypotheses:

1. Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures,
2. Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures, and
3. Enrollees report an increase in their self-reported health status over the duration of their enrollment.

Provisional Hypotheses:

1. *We will conduct a descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures,*
2. *Descriptive analysis of behavioral health conditions among enrolled children (i.e. rate/proportion of children suspended or expelled), and*
3. *Descriptive analysis of educational delays among enrolled children (i.e. rate/proportion of children receiving special education services, i.e. individual education plans "IEPs", early preschool performance, and reading and math scores at end of grades 3, 4, and 5).*



Domain 4: Lead Hazard Investigation

Hypothesis 4: *“The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program.”* Hypothesis 4 included two sub-hypotheses to address: 1) ongoing monitoring of the blood lead levels (BLLs) of all eligible children who were living in Flint at the time of the water crisis regardless of BLL status at the time of crisis and 2) ongoing surveillance of the beneficiaries who may have had continued exposure to lead (e.g. water pipes, lead in the home).

The evaluation team originally identified administrative health care records as the source to test these hypotheses. In response to difficulty framing the data pulls and the existence of pertinent data outside of the Medicaid program, questions were again added to the enrollee survey.

Methodology

Evaluation Design

The approved evaluation plan located in Appendix 2 proposed a pre-post design to evaluate the degree to which the FME met the overarching goal to identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards. The timeframes were originally anchored around April 1, 2014 as that date coincided with the **approximate** date of the water switch. This date was originally selected so that the annual reporting of administratively derived measures regarding enrollee characteristics could reach back to a twelve-month time period prior to the water switch and then follow over time accordingly after exposure to the contaminated water. As the evaluation team moved forward to assessing FME services, the anchor point was **adjusted** to May 1, 2016 to coincide with the **approximate date of the waiver enrollment**. Thus, critical timeframes for the purposes of the evaluation were revised to May 1, 2013 – April 30, 2014 as “pre” water switch time period and each subsequent year following this time period starting May 1, 2014 considered “post” water switch with FME benefit implementation effective May 1, 2016. The timeframe of **May 1, 2014** – April 30, 2016 was considered “pre” FME implementation and each subsequent year since **enrollment into FME as of May 2016** considered “post” FME implementation.

Table 1 is repeated here as a ready reference of the main timeframes.

Table 1: Evaluation Timeframe Reference

Timeframe Code	Timeframe Description
T1	baseline year prior to the water switch (May 1, 2013 – April 30, 2014)
T2	post water switch, FME not implemented (May 1, 2014 – April 30, 2016)
T3	post water switch, FME implemented (May 1, 2016 – present)

Target and Comparison Populations

Another design strategy of the evaluation proposal was to test a variety of comparison groups in addition to the pre-post design. The evaluation team considered a variety of potential comparison groups. The target population of the FME included those individuals known to be at risk for adverse outcomes related to lead exposure via the Flint Water system and included:

- Any pregnant woman and/or child up to age 21 with a household income up to and including 400% of the Federal Poverty Level (FPL) who has been served by the Flint



- water system on or between 4/1/2014 and the date water is deemed safe (Date to be determined).
- Any child born to a pregnant woman served by the Flint water system during the specified time period. The child will remain eligible until age 21.
 - Exposure was defined as consumed water drawn from the Flint water system during the specified time period and
 - resides or resided in a dwelling connected to Flint water system service lines;
 - is employed and/or had employment at a location served by the system; or
 - is receiving or received child care and/or education at a location connected to this system.

The Eligibility Protocol further clarified the criteria to include individuals who were incarcerated or who resided in a health care facility at a location served by the Flint water system. Four potential comparison groups were identified in the original proposal:

1. Medicaid beneficiaries residing in the target Flint area based on water exposure map in the year prior to the water switch.
2. Commercially insured individuals in Michigan.
3. Communities known to have similarly elevated lead exposures.
4. Beneficiaries covered through Michigan's Serious Emotional Disturbances (SED) waiver.

Each of these was associated with limitations. The main concern for Comparison Group 1 was that even if these beneficiaries had similar water lead exposure prior to the water switch, they would not have similar exposure after the water switch. The main concern for Comparison Group 2 was inability to acquire commercial insurance data. The main concern for Comparison Group 4 was the relatively small number of beneficiaries enrolled in the SED waiver and the significantly greater need for services these individuals are known to require. Enrollment criteria for the SED is an important factor in causing this group to not be a suitable comparison group. Specifically, SED waiver enrollment requires an individual to meet criteria for admission to the state inpatient psychiatric hospital. Upon reflection of the cohort in Comparison Group 4, the evaluation team concluded the groups were more dissimilar than similar which compromised their ability to serve as comparators. Thus, we focused on exploring communities potentially having similar elevated lead exposures identified as Comparison Group 3.

Unfortunately, Group 3 was compromised by the low numbers of persons having EBL (Table 2).



Table 2. Number of children under 6 years with elevated blood lead level in Genesee & Saginaw counties

Race/ethnicity	FME status	Males				Females			
		5/16 - 4/17	5/17 - 4/18	5/18 - 4/19	5/19 - 4/20	5/16 - 4/17	5/17 - 4/18	5/18 - 4/19	5/19 - 4/20
non-Hispanic White	non-FME	26	25	27	23	32	27	23	35
non-Hispanic White	FME	30	20	17	*	21	12	12	7
non-Hispanic Black	non-FME	19	27	30	32	23	17	24	21
non-Hispanic Black	FME	39	32	21	12	51	20	16	12
Hispanic/Other	non-FME	*	10	9	7	8	8	8	9
Hispanic/Other	FME	*	*	*	*	*	*	*	*
Unknown	non-FME	*	*	*	6	8	6	10	*
Unknown	FME	*	*	*	*	*	*	*	*

*Cells less than or equal to 5 suppressed

Ultimately, the evaluation team developed a more robust Comparison Group 5.

- ***Beneficiaries with similar individual and neighborhood characteristics at the census tract level.***

A variety of statistical methods were applied during 2020 resulting in identifying Saginaw County as a reasonable community comparison. The evaluation team considered two main approaches in the selection of Comparison Group 5 (see Appendix 7 for more detail). In the first approach, we considered the K means method¹⁰ to find a lower-peninsula county like Genesee County in health outcomes, health behavior, clinical care, social economic environment, and physical environment. These vital health factors are used by the Robert Wood Johnson Foundation and the University of Wisconsin Population Health Institute to rank counties in the U.S.¹¹. We chose these confounding characteristics (a total of 48 variables) under the assumption that counties with similar characteristics affecting lead exposures would have similar levels of lead exposures. We used the Gap statistic⁸ to first estimate the number of clusters in the data and then used 5,000 random starting values to run the K means algorithm to count how many times a county was assigned to the same cluster as Genesee County. The county that was most often clustered together with Genesee County was chosen as the comparison county. The evaluation team used this method for a similar evaluation project.¹⁰

The second approach the evaluation team considered was the synthetic control (SC) method.⁹ Since no single county was as like Genesee County in all characteristics under consideration, we explored using a weighted combination of counties as the “control” county. The key data



for this approach was the Michigan Childhood Lead Poisoning Prevention Program Data Report series from 2012 to 2017. The SC idea is to impute a counterfactual outcome of Genesee as a weighted average of other lower peninsula counties. The weights are computed by minimizing a vector distance between Genesee and other counties over a set of pre-treatment covariates that are predictive of the outcome (e.g., elevated BLL). A limitation of the SC method is that it requires re-calibration of weights for each hypothesis because different counterfactual weights may be required to construct a synthetic control that is similar in the respective hypothesis being tested. Summary measures at the county level for each hypothesis several years prior to the water switch or waiver expansion will also be required. County level estimates of the majority measures identified for this evaluation are not available.

Both approaches were limited by data availability and comparisons would have been ideal at the city level. The cities of Pontiac and Saginaw were considered as they were similar in size, racial composition, socioeconomic distress, initial development, economic trajectory, and current housing landscape as Flint. Thus, risk factors for lead exposure may also be similar across all three communities. Pontiac was additionally suitable as a comparison community because, like Flint, it has been served by the Great Lakes Water Authority (formerly the Detroit Water & Sewerage Department). These communities further share the existence of a spread of wealthier suburbs surrounding them which may offer comparison opportunities. Additional potentially suitable communities included the smaller metropolitan areas of Jackson, Muskegon, and Kalamazoo. However, city-level data were difficult to obtain which made it difficult to quantify the similarities. Thus, we restricted our choice of geographic comparison group to the county level.

The K-means analysis confirmed that Saginaw County would be a suitable option for Comparison Group 5. Upon identification of the comparison community, the MDHHS Data Warehouse was accessed for claims/encounter data for all Medicaid enrollees residing in Saginaw County from May 2013 through April 2020. History of comorbidity and/or census-tract level social/economic background were adjusted when appropriate in regression models. A more robust description of the procedure and analyses for selecting the comparison group is described in the Preliminary Results section and Appendix 7.

Evaluation Period

The FME approval was for the time period 3/3/16 - 2/28/21 with a state identified **enrollment** date of 5/9/16. Upon CMS approval of the evaluation proposal 8/8/17, the evaluation team began preparing to commence the evaluation during the contracting period. Formal evaluation activities began January 2018. The evaluation timeframe **was identified as** 1/1/2018 through 4/30/2021 allowing a sixty-day period to finish up a final report after the **original** waiver period



expired. This cumulative interim report is provided upon request as an element of a waiver extension application. Results described should not be interpreted as final. Additionally, not all hypotheses have been formally addressed as of the date of this report. Generally, data collection protocols for administrative health care data were established during calendar year 2018 while enrollee, TCM provider and MDHHS key informant survey protocols were implemented during calendar year 2019.

This report was updated November 2020 to provide information about remaining activities and data sources. Another update was provided May 2021 to provide additional detail regarding comparison group selection. Administrative data sets were extended to run through April 30, 2020 and data obtained from the MDHHS Data Warehouse for FME enrollees as well as the comparison group. These data are being cleaned and updated tables will be available in the 2020 Evaluation Annual Report. Despite the pandemic, Waves 2 and 3 of the enrollee surveys were able to be implemented. Longitudinal analysis comparing enrollee responses from Wave 1 to Wave 2 is in process and we anticipate having results available in the 2020 Evaluation Annual Report. Wave 3 survey data collection will conclude December 2020 and will be incorporated into the final evaluation report. Additionally, a follow-up Key Informant Interview was conducted with the TCM Case Managers. Those results will be included in the 2020 Evaluation Annual Report which will be submitted by February 28, 2021.

The evaluation team will obtain final determinations regarding permission to access outstanding datasets including the Michigan Care Improvement Registry (MCIR) and Maternal Infant Health Program (MIHP) program. Requests to access these data were submitted again in October 2020 and we expect a final determination regarding access by December 2020. These sources are both intended to supplement existing claims/encounter data already in-house. MCIR could be helpful in identifying immunizations provided to enrollees that were not billed to Medicaid. An inability to obtain these data might result in an underestimate of immunization rates as reported in the evaluation. The MIHP program maintains assessment data which would be informative to support additional information regarding referrals and lead exposure requiring screening. Lack of these data would also contribute to evaluation results underestimating referral activity in the evaluation.

Existing activities have not used Vital Records data. Originally, this source was thought to be needed to obtain reliable birthweight information. Since October 1, 2014, Michigan Medicaid policy has required submission of birthweights on delivery encounters from all fee-for-service and managed care providers. Thus, the evaluation team has had access to these data points since that time. IHP was involved in separate work with MDHHS to validate claims/encounter reported birth weights to Vital Records documented birthweights. The specific validation measure was to determine the proportion of births where the difference between the claims/encounter birthweight and the Vital Records birthweight was greater than 30 grams.



The results identified less than 8% of total observations (n=44,116 births) showed a difference of more than 30 grams and both intraclass correlation coefficient and Cronbach's alpha were greater than 0.9 showing excellent reliability and consistency between the two data sources. Thus, the evaluation team felt confident using the claims reported sources. However, IHP continues to pursue Vital Records data as it will contribute to the baseline information (T1) timeframe and may further be useful to establish prenatal care dates more robustly than relying on claims/encounter data. As of November 2020, access to these data is approved and will be acquired prior to the end of the calendar year 2020.

Due to the prescribed pre-post design and the predominant reliance on administrative datasets for many of the evaluation sub-hypotheses, the full time period of health care claims/encounter and blood lead testing data reached back to 5/1/13 or one year prior to the water switch to provide baseline estimates. While this allowed one month of “post water switch” to be included in the baseline timeframe, the impact on measure reporting was believed to be negligible.

Evaluation Measures

Again, the overarching goal of the FME was to identify and address any physical or behavioral health issues associated with actual or potential exposure to lead hazards. Thus, specific evaluation measures were selected for their relevance to known impacts of lead as a neurotoxin on developing physiological systems. In addition, recommended measures of preventive and screening services were included. The waiver also authorized individuals at higher income levels to qualify, offering a chance to measure uptake in targeted services across socioeconomic levels. The summary matrix of all measures by domain and steward is available in Appendix 1.

The specific evaluation measures associated with Hypothesis 1, “*Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure*”, included specific Health Plan Employer Data Information Set (HEDIS) measures endorsed by the National Quality Forum (NQF).⁴ The selected measures included:

- Age-appropriate well-child exams;
- Age-appropriate developmental screening;
- Age-appropriate blood lead testing;
- Appropriate re-testing for individuals with elevated blood lead levels;
- Timely prenatal and postpartum care for pregnant women; and
- Recommended blood lead testing for pregnant women.



The remaining measures included items that were specific to Michigan. For instance, participation in a program intended to support positive birth outcomes, the Maternal Infant Health Program (MIHP) was added. It was expected that individuals receiving TCM supports would be more likely to receive referrals and participate in MIHP.

The evaluation team felt it was important to solicit feedback directly from FME participants to ascertain whether the expanded eligibility and TCM services supported them in accessing services. An enrollee survey was designed to address the final two measures:

- Beneficiary attestation to improved access to health care; and
- Beneficiary report of improved satisfaction with ability to access health care.

Hypothesis 2 focused on the additional TCM service added as a new benefit with the waiver. The hypothesis was *“Enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure.”* The intention of this benefit was to facilitate needed medical, social, educational and other services for those who were exposed to the contaminated water. TCM provided an opportunity for enrollee education and support as well as assistance navigating the health care system and helping to mitigate barriers to care. Therefore, the measures associated with the sub-hypotheses were selected for their significance to the operational and implementation aspects of the benefit. As such, these measures were specific to Michigan.

- Use of referral services by TCM participation level;
- Proportion receiving annual TCM assessment;
- Proportion of TCM participants having well-child exams will exceed proportion by non-TCM participants; and
- Proportion of TCM participants having developmental screenings will exceed proportion by non-TCM participants.

Hypothesis 3 in the waiver application addressed improved health outcomes. This reflected the overall goal of the FME waiver, *“Enrollees will have improved health outcomes compared to others with similar levels of lead exposure.”* Because the full impact of lead exposure on a child’s developing nervous system cannot be assessed for several years, three process measures were identified as proxies for clinical outcomes.³ Process measures validated by national organizations were used to measure clinical outcomes based on known associations between these metrics and general health status.⁴

- FME enrollees will have greater age-appropriate immunization completion;
- Pregnant FME enrollees will deliver infants with greater birth weights; and
- Self-reported improvement in health status.



As the enrollee survey was designed, the potential for TCM providers to impact enrollees holistically with their health care needs was realized. The TCM providers were acknowledged to have opportunities to ensure appropriate referrals and services for a host of health conditions including chronic conditions. Thus, several additional questions regarding chronic disease and self-management capacity were included in the enrollee survey to inform evaluation questions regarding changes in health status.

This domain also included three *provisional* hypotheses regarding educational measures and performance. These measures were developed in-house. The following measures were deemed provisional due to concerns regarding the appropriateness of children enrolled in the Severe Emotional Disturbance (SED) waiver as a comparison and/or the availability of the necessary data to fully investigate them.

- ***Provisional Hypothesis 3.4: We will conduct a descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.***
- ***Provisional H3.5: Descriptive analysis of behavioral health conditions among enrolled children (i.e. rate/proportion of children suspended or expelled).***
- ***Provisional H3.6: Descriptive analysis of educational delays among enrolled children (i.e. rate/proportion of children receiving special education services – IEPs, early preschool performance, reading and math scores at end of grades 3, 4, and 5)***

Information regarding prevalence of behavioral health conditions and educational delays was collected from parents/guardians of children enrolled in the waiver. The enrollee survey was the vehicle used to obtain these self-reported data. ***The other source originally targeted was individual level reporting collected by the Michigan Department of Education (MDE). Unfortunately, the request to access MDE individual level data to support this work was denied due to FERPA regulations. The federal Department of Education would not provide a waiver to the state for this work. Therefore, the evaluation team has pivoted to use the parent/guardian self-reported data from the beneficiary survey along with publicly available reporting through MI School Data.***

The publicly available Mi School Data dashboard allows users to access aggregate data from Michigan Schools pertaining to early childhood through high school. Data may be reported at the individual school level or aggregated to the district level. Available metrics reported through Mi School Data include participation in early childhood programs, grade progression (i.e. students retained in grade), and educational delays. Four-year graduation and drop-out rates are also available. Continuity of special education services is reported both for the Early Childhood period including pre-Kindergarten as well as through secondary education.



Distribution of selected disabilities is available. State standardized testing is reported through the dashboard including performance at 3rd, 4th, 5th, 6th, 7th, and 8th grade content. However, a gap in state testing was experienced during the 2020 COVID-19 pandemic and will be unavailable. We will target district level reporting due to the inability to match enrollees with specific school of enrollment. It is less granular and unfortunately, cannot be used to determine if students were simultaneously enrolled in the FME waiver. However, it does provide a means to pull similar measures for our identified comparison community (Saginaw County).

It is noted that Flint and Genesee county have a total of 22-25 school districts that serve the area. The organization of the districts is distinct from many other Michigan counties because of the presence of numerous charter schools. The Flint Community School District (FCSD) is the largest school district, but not all FME enrollees attend FCSD. An additional complexity to Michigan schools is the state's Schools of Choice policy. This permits students to attend schools outside of the district in which they reside. Some estimates are available through the Mi Schools dashboard reflecting student mobility which may inform the relative stability of the student population.

The evaluation team had further anticipated a collaboration with the Neurodevelopmental Center of Excellence (NCE) to identify summary data of those children who were referred for behavioral or cognitive issues from schools, doctors or the Flint Registry. NCE began operations in 2019 and unfortunately were required to suspend services during the COVID-19 statewide executive order in early Spring 2020. The number of children served, either screened or fully assessed, were 293 for 2019. Of those, approximately 67% received intervention services. Ongoing outreach with NCE is occurring to identify whether additional descriptive information is available beyond referral source and counts that may be shared to inform the evaluation.

Hypothesis 4 referenced the Lead Hazard Investigation that was expanded through the FME waiver, “The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program.” Mitigation or abatement efforts to home sites with lead hazards were not funded through this expansion. The FME waiver did authorize the use of funding to conduct screening and assessment of environments to assist with case finding. Prior to the waiver, documentation of an elevated BLL was necessary in order to refer a property for lead exposure investigation. This requirement was relaxed by the FME waiver so that home sites could be assessed even in the absence of an elevated BLL. The details of environmental assessments and mitigation efforts are supported and documented by governmental agencies outside of Medicaid compromising the evaluation team’s ability to quantify levels of lead exposure. Thus, developed metrics took into consideration the effect of



additional Medicaid funds' in facilitating additional screening and case finding. The enrollee survey was again targeted to provide some information regarding ongoing lead exposures.

- Prevalence of lead hazard assessment/investigation; and
- Prevalence of those at risk for ongoing lead exposure receiving referrals for additional environmental investigation.

Data Sources

Major sources of data identified as necessary to address the evaluation measures thus far have included: 1) the MDHHS Health Services Data Warehouse, 2) TCM program information, 3) Beneficiary surveys, 4) Provider Key Informant Interviews, 5) Michigan Childhood Lead Poisoning Prevention Program Data Report, and 6) Michigan Care Improvement Registry data. MDHHS maintains a data warehouse containing information at an individual level regarding a variety of health-related services and data points. **Publicly available reporting including MI Schools Dashboard, County Health Rankings and census tract data from the American Community Survey were identified as additional data sources.** IHP employs staff with the necessary permissions and expertise to access the MDHHS Health Services Data Warehouse and acquire the elements needed to support analyses. However, despite the storage of a variety of health-related program data in the Health Services Data Warehouse, access to these data are controlled by each program. IHP staff having access to Medicaid claims/encounter data did not have access to the Lead Poisoning Prevention or Care Improvement registry data on the onset of the evaluation. During the first two years, access to the Lead Poisoning data has been granted however remained pending for the Michigan Care Improvement Registry program. **Second requests have been submitted for access to these data in October 2020. However, should access not be granted, the evaluation team believes that the results reported through available administrative data sources would reflect an undercount of the actual number of services rendered thus introducing a conservative error.**

MDHHS Health Services Data Warehouse – Enrollment and Utilization

Specific targets contained within the data warehouse included Medicaid eligibility/enrollment, final paid Medicaid claims/encounter data, blood lead program data and immunization data. While much of the Medicaid claims/encounter data lack clinical care values, the **Michigan Childhood Lead Poisoning Prevention Program** does collect this information. The State of Michigan further maintains a master person index to facilitate matching of individuals between different programs so that individuals covered through Medicaid will be linked to their blood lead testing dates and values when present. Moreover, the lead program data is not restricted to include only those covered through Medicaid, thus it may provide opportunities to shed light on conditions of potential comparison groups. The Michigan Care Improvement Registry (MCIR)



collects immunization data that is required reporting by health care providers. Like the lead program data, the evaluation team would theoretically be able to link an individual's immunization record to their Medicaid data via the master person index given appropriate access. Also, data on individuals covered through other forms of insurance or receiving immunizations funded through programs besides Medicaid will be present in MCIR as the team explores potential comparison groups. Evaluation team members already had access to the eligibility, enrollment and health care claims data. Approval was needed for the blood lead program as well as the MCIR data. To date, access to the blood lead program has been granted ***and blood lead levels at the individual level have been acquired. An additional request for MCIR data has been submitted October 2020 and we expect a final determination regarding access by December 2020.***

Ongoing review of routinely reported information is conducted by MDHHS program and warehouse staff to identify potential issues with data loading or when changes to warehouse tables are made. The evaluation team did not validate the data extracted from the warehouse with primary sources such as medical record reviews. Instead, conversations between the IHP staff responsible for pulling data and state program staff occurred and continue to occur to ensure that relevant fields are captured, and coded variables are correctly interpreted. For example, an issue with the completeness of the blood lead program was identified resulting in a repull of the data once IHP had been advised of the correction. Data review is an ongoing, iterative process and continues throughout the duration of the evaluation. Independent review and validation of code used to process data and conduct statistical analyses was performed by evaluation team statisticians.

Targeted Case Management Program Information

The supplementary TCM benefit approved in the waiver necessitated additional data sources to support the evaluation beyond the claims/encounter information contained in the MDHHS Health Services Data Warehouse. While the provision of TCM services were identified through specific procedure codes entered onto billing data, the ability to discriminate between specific services was not available via this administrative data. For example, the TCM provider could assist a beneficiary to schedule a medical appointment or arrange for transportation. The allowable procedure codes would not permit the evaluation team to monitor which of these two services was most needed. This level of detail was ***presumed to be*** available through electronic medical record documentation among visit summaries or progress notes. Therefore, the evaluation team established a Business Associates' Agreement (BAA) with Genesee Health System (GHS) to authorize access to their electronic medical records (EMR) for purposes of this evaluation. GHS was successful in working with their EMR vendor to set up summary reporting for the evaluation team. However, the detailed progress notes have been found to not be amenable to extraction in a format readily suited for analyses. ***Further, the nature of documentation was found to be insufficient to discriminate between referrals to address***



needs associated with the water exposure versus referrals to address other pre-existing or concomitant social, physical, or behavioral needs. GHS has been supportive in extracting some process measure tracking for the evaluation team. Ongoing efforts to use these data elements will be explored in the remaining evaluation period.

An additional data source regarding the TCM benefit was a key informant interview conducted with individual(s) employed to serve as TCM providers. These data were obtained through a telephone survey implemented during the second quarter of 2019. A discussion guide was established to facilitate consistency of information and one registered nurse staff member from IHP conducted all the telephone interviews. The draft summary report was shared with the informants to ensure accurate representation of their information. ***Follow-up interviews with the TCM providers were implemented during 2020.*** Refer to Appendix 4 for the TCM Key Informant Interview summary and associated documentation.

Beneficiary Survey and Reporting

Enrollee survey data represented the last major source of data to inform the evaluation. Key measures of the evaluation such as inquiries regarding improvements in access to care or health outcomes required input from those enrolled in the FME waiver. The original survey plan was to conduct three survey waves approximately twelve months apart to capture trends over time. Modifications to the original survey plans were necessary due to the time period involved with evaluation plan approval and contracting. This original design was modified to maintain three waves but have each wave spaced approximately nine months apart. Methods for survey participation were further expanded from the original design based on feedback from Flint community members. The original survey design called for a paper or phone-in survey. A web-based component was added in time for the first wave's dissemination based on community feedback. The evaluation team requested and received approval to offer a small monetary incentive to complete the survey. Flint community residents have been inundated with academic and non-academic projects and programs operating in the area; therefore, the evaluation team was concerned that survey fatigue could adversely affect participation.

Wave 1 was conducted from December 2018 through March 2019. All paper surveys were blind double data entered. Surveys completed by telephone were subjected to monitoring by supervisory staff. Web-based responses to the survey were directly entered by the respondent. In addition to using a two-factor authentication process for a selected respondent to access the online survey, the web survey allowed only one response per unique credential. This prevented respondents from completing more than one survey. The online survey was further protected from non-FME enrollee participation by restrictions imposed on the ability of internet search engines to locate the survey. Refer to Appendix 3 for copies of the wave 1 survey tools.



Wave 2 was conducted September 2019 through March 2020 and Wave 3 was implemented July 2020 and is currently collecting data. The anticipated loss to follow-up was lower than expected with 64% of Wave 1 participants completing Wave 2. These data are currently being analyzed and findings will be presented in the 2020 Evaluation Annual Report.

Analytic Methods

Tests of significance (Chi-square and t-tests, etc.) to ascertain group differences and change over-time are planned to monitor the measures that are being tracked on an annual basis. Future comparisons of measures will be tested using identified cluster-robust methods accounting for the potential nesting of observations within the same individual. Because the expansion criteria have the potential to change the population composition of enrolled individuals over time, the evaluation team monitors the population composition.

Beneficiary Survey Sample Selection

The population eligible to participate in the initial survey wave were those enrollees who had at least six months of continuous enrollment in the FME waiver and were enrolled as of November 1, 2018. This inclusion criteria resulted in 24,082 unique beneficiaries being identified. The sample was selected in two stages to identify a sample pool of 11,453 for Wave 1. In the first sampling stage, the sampling frame was divided into three groups based on the beneficiary's residence. These residential categories were selected upon the evaluation team's recognition that the FME waiver enrolled individuals were more geographically dispersed than what had been hypothesized. The categories established included:

- Only Genesee County – included beneficiaries who only appeared to only reside somewhere in Genesee County based on the available enrollment record history.
- Partial Genesee County – included beneficiaries who resided both in and out of Genesee County based on the available enrollment record history.
- Never Genesee County – included beneficiaries who had no enrollment data to suggest they ever resided in Genesee County. However, these individuals were flagged as being enrolled in the FME waiver and therefore were included.

We applied stratified random sampling by residence category resulting in 11,453 potential participants for Wave 1 (refer to Table 3). Among those in the Only Genesee category, we randomly selected 10,000 beneficiaries. In the second stage, we applied the probability proportional to size (PPS) sampling based on the size of the age category. However, due to the small number of enrollees in the Partial Genesee Category, the team elected to oversample and retain all individuals identified regardless of Age Category (n=384). We further included all beneficiaries in the Age Category 23-64 years as of November 1, 2018 regardless of residence

category due to the small number of individuals (n=87). For the Never Genesee category, the team randomly selected 1,000 beneficiaries for survey participation. The total number of beneficiaries selected for survey inclusion were then equally split into four batches to manage the mailing process.

Table 3. Number of beneficiaries selected for survey sample out of total eligible population

	Age Category (Years)	Residence Category			Total N (%)
		Only in Genesee N (%)*	In and Out of Genesee N (%)	Never in Genesee N (%)	
Population Count	0-6	7,657 (31.8)	163 (0.7)	855 (3.6)	8,675 (36)
	7-17	11,791 (49.0)	181 (0.8)	1,051 (4.4)	13,023 (54.1)
	>=18	2,136 (8.9)	40 (0.2)	208 (0.9)	2,384 (9.9)
	<i>Total</i>	<i>21,584 (89.6)</i>	<i>384 (1.6)</i>	<i>2,114 (8.8)</i>	<i>24,082</i>
Sample Selection Count	0-6	3,559 (31.1)	163 (1.4)	404 (3.5)	4,126 (36.0)
	7-17	5,480 (47.8)	181 (1.6)	497 (4.3)	6,158 (53.8)
	>=18	1,029 (9.0)	40 (0.4)	100 (0.9)	1,169 (10.2)
	<i>Total</i>	<i>10,068 (87.9)</i>	<i>384 (3.4)</i>	<i>1,001 (8.7)</i>	<i>11,453</i>

*Proportions reflect sub-category representation among the Total Count of all Enrollees

The nearly 50% population was selected because of the longitudinal nature of the survey. The evaluation team was concerned with retaining sufficient numbers for analysis at the end of Wave 3. The time period required to implement all three waves was eighteen months. A larger than normal sample was also deemed necessary based on concerns regarding the level of participation among these individuals who have been inundated with survey requests by a multitude of organizations. The evaluation team received anecdotal reports that some attorneys recommended area residents against participating with surveys due to possible future civil litigation. The impact of these recommendations on survey response rate was unable to be quantified.

Beneficiary Survey Response Rate

Wave 1 results can be considered baseline results for comparison to forthcoming survey waves. Of the 11,453 surveys that were sent out in four batches, 2584 or 22.5% of participants responded. The association between mailing batch and rate of survey response was not statistically significant (p=0.07). Since there was no batch effect for mode of response, all batches were combined to create a single cohort of respondents. Of the 2584 returned surveys, 2359 (91.3%) were child and 225 (8.7%) were adult. Ultimately, 2356 of the child surveys had usable data for reporting.



Table 4. Number of Survey Participants out of Total Sample Selected

	Age Category (Years)	Residence Category			Total N (%)
		Always in Genesee N (%)	In and Out of Genesee N (%)	Never in Genesee N (%)	
Sample Selection Count	0-6	3,559 (31.1)	163 (1.4)	404 (3.5)	4,126 (36.0)
	7-17	5,480 (47.8)	181 (1.6)	497 (4.3)	6,158 (53.8)
	>=18	1,029 (9.0)	40 (0.4)	100 (0.9)	1,169 (10.2)
	<i>Total</i>	<i>10,068 (87.9)</i>	<i>384 (3.4)</i>	<i>1,001 (8.7)</i>	<i>11,453</i>
Survey Participants	0-6	808 (31.3)	31 (1.2)	88 (3.4)	927 (35.9)
	7-17	1,276 (49.4)	43 (1.7)	113 (4.4)	1,432 (55.4)
	>=18	198 (7.7)	6 (0.2)	21 (0.8)	225 (8.7)
	<i>Total</i>	<i>2,282 (88.3)</i>	<i>80 (3.1)</i>	<i>222 (8.6)</i>	<i>2,584</i>

*Proportions reflect sub-category representation among the Total Count of Sampled Enrollees

The response by online method was the most frequent. During the initial planning, the prevailing belief was that these beneficiaries would not be able to access internet-based surveys. Also, the evaluation team believed that implementation of full online modality without email addresses would potentially limit distribution. However, in response to community suggestions, the online modality was added as an initial option with the opportunity for respondents to provide email addresses for future waves. In fact, over 70% of these who participated in Wave 1 provided an email address for Wave 2. To date, those who were notified and provided the survey internet link by email exceeds 50%.

Wave 2 survey invitations were distributed September 2019 through March 2020. Again, the online response option was the most frequent survey participation method. Nearly two-thirds, 64%, of Wave 1 participants completed the Wave 2 survey. Data entry of the hard-copy responses was adversely affected by the State of Michigan’s Stay-Home order as this work was deemed non-essential. This activity received approval to resume July 2020. These data are currently being analyzed and findings will be presented in the 2020 Evaluation Annual Report.

Wave 3 distribution was also implemented July 2020 and is currently collecting data. We will close data collection December 31, 2020. As of November 2, 2020, approximately 54% of Wave 1 participants have completed the Wave 3 survey.

Additional Considerations

IHP engaged in discussions with MDHHS and CMS regarding evaluation tasks and activities during the evaluation approval and contracting process. Upon execution of the contract, the evaluation team submitted the project to the MSU Institutional Review Board for review. The

project was determined to not meet the definition of research on 1/22/18 and is considered exempt (refer to Appendix 5).

The evaluation team communicated and met regularly in formed work groups to ensure progress and efficiency. All evaluation team members are members of the Full Workgroup with topical workgroups established to focus attention and activities on discrete elements of the FME workplan (see Table 5). In addition, activities of the evaluation team included day-to-day communication to troubleshoot and resolve questions as they arise. Drs. Oberst and Ford remain responsible for project supervision.

Table 5: Flint Medicaid Evaluation Workgroups

Workgroup Title	Frequency	Purpose
Full	Monthly	Full team meets regarding progress and communication between the other workgroups.
Survey	Bi-Weekly	Design and administration of the beneficiary surveys. Communication with Flint community partners to avoid duplication and beneficiary surveys. Design and administration of TCM key informant interviews.
Data	Bi-Weekly	Updates on data preparation, data management and analyses. Creating data files to include target variables.
Community Asset Inventory	<i>Disbanded</i>	Create and maintain inventory of all community entities and key stakeholders that provide services related to Flint Water Crisis. Communication with major key stakeholders to inform the evaluation.
Education	As Needed	Ongoing communication with Flint Community Schools, Genesee Intermediate School District, GHS, Neurodevelopmental Center of Excellence (NCE), and other key stakeholders. Utilize MI Schools Data to address educational progression and NCE data for behavioral/developmental outcomes.

Community Asset Inventory

The project team identified a partial inventory of community partners and resources that provided support to those affected by the water crisis. At the onset of the recognition of the water crisis, community agencies and private and public non-profit organizations offered services and supports and were positioned for more rapid response than governmental agencies. Many volunteers and community-based organizations served at various points without formal acknowledgement. The federal declaration enabled governmental agencies to work with the affected community after many of these other organizations were already



operational. Federal resources were likely to be formally documented while the bulk of community-based volunteer activities were not. The evaluation team had hoped to identify and categorize this information.

During calendar year 2019, the Community Asset Inventory workgroup identified community fatigue with respect to revisiting the efforts of the many organizations that had entered the region after the water crisis was made public. Specifically, individuals expressed concern that accurate and reliable information was unavailable. The evaluation team fielded questions regarding the relevance of this information obtained so remotely from the initial insult as well as concerns regarding increasing anxiety levels by revisiting the immediate responses. In deference to the community's concerns, the Community Asset Inventory group was disbanded during calendar year 2019 in favor of using existing information (press releases, announcements, etc.) that might be sourced through major media to provide examples of the types of organizations that could have supported individual community member needs. This work was intended only to provide possible context for observed trends. The evaluation team agreed that hypothesis testing activities would not be unduly limited by the lack of these data.

Education Data

Several meetings were held with representatives from the MDE. Adverse impacts of lead can be identified through learning delays and behavioral problems. Thus, discussions were held regarding permissions to link children covered through the Medicaid waiver to MDE data. MDE representatives clarified FERPA restrictions and explained that an exemption from the federal government would be required to access data at the individual level. Unfortunately, the federal Department of Education declined to provide this exemption.

Due to the inability to link at the individual level to existing Medicaid data, the evaluation team pivoted to evaluate the potential to use publicly available summary reports. A process to utilize MDE data in aggregate to include the MI Schools Dashboard/Database to track developmental and educational outcomes was identified and will be implemented in 2020. ***MI School Data dashboard provides access to aggregate data from Michigan Schools pertaining to early childhood through high school. Data elements include participation in early childhood programs, grade progression, and educational delays. The dashboards available for Early Childhood describe those programs that are intended to prepare children for kindergarten (e.g. EarlyOn, Head Start, Great Start Readiness Program, etc.). Specific reporting includes information on overall program participation as well as initiation and continuity of special education services. The K-12 Grade dashboards have a variety of student and school performance metrics available. The evaluation team intends to target graduation and drop out rates, data on proportion of students retained in grade (i.e. held back from progressing) and Grades 3-8 State Testing performance. The State Testing platform has changed from MEAP to M-STEP since 2013 so this may cause gaps in overall longitudinal reporting. Lastly,***



special education information is reported including proportion having certain disabilities, age, gender and educational setting. Historical data is available back to the 2012-2013 school year and can be geographically restricted. Thus, we will be able to report on Genesee and Saginaw school districts. As previously mentioned, we will be unable to determine the experience of children specifically enrolled in the FME Waiver.

The Neurodevelopmental Center of Excellence (NCE) was added to the Genesee Health System in 2018 and become fully operational in January 2019. Genesee Health System is the county's public mental health provider. The NCE offers neuropsychological assessments to children and individuals impacted by the Flint Water Crisis. Due to the mandated closures, the number of children served were adversely impacted during 2020. Therefore, the evaluation team will not attempt to match individual FME enrollees with clients at the NCE and the Mi School Data will be the primary data source. We have reached out to NCE to inquire if they would provide summary information such as proportion of enrollees screened, proportion referred for full assessment, and the proportion following-up with services if the evaluation team provides a list of enrollee information to serve as the denominator. If these metrics are available, we will attempt to describe how these estimates vary by FME enrollment status.

A secondary source of education-related data was incorporated through the beneficiary survey. Acknowledging the limitation of self-reported information, the evaluation team included several questions on the child version of the survey inquiring about school grade level and whether children had been identified as having learning problems or behavioral/emotional problems. The goal of these questions was to provide at least a suggestion regarding the impact of the lead exposure on educational performance.

Timeline Modification

The timeline proposed in the original evaluation plan submission required initial modification to adjust for the time required for evaluation plan approval and contracting activities. As the activities unfolded during 2018 and 2019, further adjustments were necessary as additional information regarding potential data sources became available. Although some activities were deferred to later years, the groundwork established over the first 24 months is expected to support the bulk of planned activities within the remaining timeframe. The evaluation's timeframe was based on calendar year to coincide with federal reporting timelines and as a result, activities may span more than one state fiscal year reflected as the contracting year in Table 6. A revised Evaluation Timeline is presented below along with activity status as of December 31, 2019.

As of 12/31/19, the following activities were finalized:

- Final report summarizing Wave 1 Beneficiary Survey Responses.



- Wave 2 Beneficiary Survey modifications completed, and mailing begun to the approximately 2600 Wave 1 respondents.
- Final report summarizing the TCM Provider Key Informant Interviews.
- An additional activity, Administrative Costs MDHHS Key Informant Interviews, was added and the final report summarizing these interviews was completed.

Year 3 activities are expected to continue the tasks that support the annual reporting of hypotheses established for the four Flint Waiver Expansion evaluation domains.

- MDHHS data acquisition requires annual pulls allowing appropriate time for claims run-out to ensure data completeness.
- Wave 2 Beneficiary surveys will be completed and summarized with attention to trends over time between the waves.
- Wave 2 TCM Key Informant Interviews will be completed and summarized with attention to trends over time between the waves.
- Wave 3 Beneficiary surveys will be initiated.

Table 6: Revised Timeline for Evaluation Activities

Revised Time Period	Activities	Status (as of 12/31/19)
Eval Contract Year 1: 1/1/2018 – 9/30/2018	<ul style="list-style-type: none"> • Identify key contacts for targeted data sources • Participate with Flint Registry Advisory Committee • Draft beneficiary survey • Implement Wave 1 beneficiary survey (~33 months post-enrollment target: December 2018) • Draft TCM Provider Survey/Key Informant Interview • Implement Wave 1 TCM Provider Survey/Key Informant Interviews (~34 months post TCM implementation: January 2019) • Draft community asset inventory tool • Program administratively derived measures and report for pre-exposure year (4/1/13 – 3/31/14), year 1 (4/1/14 – 3/31/15) and year 2 (4/1/15 – 3/31/16) • Assemble and test different methods to generate comparison groups • Identify and test data sources for TCM (needs assessments, plans of care, screenings, referrals, etc.) • Identify and test data sources and methods for linkage with Department of Education information (will be using publicly reported school data) • Identify research co-occurring studies and evaluation for possible incorporation into evaluation • Generate quarterly updates 	<ul style="list-style-type: none"> • Completed • Ongoing • Completed • Deferred to Year 2 • Completed • Deferred to Year 2 • <i>Eliminated</i> • Completed • Ongoing • Ongoing • Ongoing • Ongoing • Ongoing



Revised Time Period	Activities	Status <i>(as of 12/31/19)</i>
Eval Contract Year 2: 10/1/2018 – 9/30/2019	<ul style="list-style-type: none"> • Implement Wave 1 beneficiary survey (<i>From Year 1: ~33 months post-enrollment target: December 2018</i>) • Wave 1 Beneficiary Survey analysis and report findings • Implement Wave 2 Beneficiary Survey to Wave 1 participants (~40 months post-enrollment: Sept 2019 – January 2020) • Implement Wave 1 TCM Provider Survey/Key Informant Interviews (~ 32 months post TCM implementation: Jan 2019) • Wave 1 TCM Provider Survey/Key Informant Interviews analysis and report findings • Ongoing community asset inventory surveillance • Ongoing monitoring of community-based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/16 – 4/30/17 (year 1 delivery) • Run annual administrative measures and conduct analysis and trending for timeframe 5/1/16 – 4/30/17 • Monitor increase in enrollment and services for cost evaluation for timeframe(s) • <i>Drafted and implemented Key Informant Interview for Administrative Cost Summarization (Added to Year 2)</i> • <i>Administrative Cost Key Informant Interview analysis and report findings (Added to Year 2)</i> • Assemble and test different methods to generate comparison groups (<i>From Year 1</i>) • Generate quarterly updates • Generate interim annual report (Calendar Year 2018) 	<ul style="list-style-type: none"> • Completed (Dec 2018 - April 2019) • Completed • Ongoing • Completed (Jan 2019 – April 2019) • Completed • <i>Eliminated</i> • <i>Eliminated</i> • Completed • Completed • Completed • <i>Deferred to Year 3</i> • <i>Deferred to Year 3</i> • Ongoing • Ongoing • Completed (March 2019)
Eval Contract Year 3: 10/1/2019 – 9/30/2020	<ul style="list-style-type: none"> • Implement Wave 2 (Follow-Up) TCM Provider Survey/Key Informant Interviews (~42 months post TCM implementation: Jan 2020) • Research and report potential commercial comparison group estimates for expanded financial limit cohort • Continue Wave 2 (Follow-Up) Beneficiary Survey (~39 months post-enrollment: Sept 2019 – March 2020) • Wave 2 Beneficiary Survey analysis and report findings • Summarize Wave 2 TCM Provider Survey/Key Informant Interviews and report findings • Implement Wave 3 (Follow-Up) Beneficiary Survey (~48 months post-enrollment: June 2020) 	<ul style="list-style-type: none"> • Pending • Pending • Ongoing (will extend through March 2020 due to timing of Wave 1 responses) • Pending • Pending • Pending



Revised Time Period	Activities	Status <i>(as of 12/31/19)</i>
	<ul style="list-style-type: none"> • Ongoing community inventory surveillance • Ongoing monitoring of community-based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/17 – 4/30/18 • Run annual administrative measures and conduct data analysis/trending for timeframe 5/1/17 – 4/30/18 • Monitor change in enrollment and services for cost evaluation (<i>From Year 2</i>) • Generate quarterly updates • Generate cumulative, interim evaluation report (Calendar Years 2018-2019) 	<ul style="list-style-type: none"> • <i>Eliminated</i> • <i>Eliminated</i> • Ongoing • Ongoing • Ongoing • Ongoing • Ongoing (January 2020)
Eval Contract Year 4: 10/1/2020 – 4/30/2021	<ul style="list-style-type: none"> • Continue Wave 3 Beneficiary Survey (~48 months post-enrollment: June-Oct 2020) • Summarize Wave 3 Beneficiary Survey analysis and report findings • Implement Wave 3 TCM Provider Survey/Key Informant Interviews (~54 months post TCM implementation: Jan 2021) • Summarize Wave 3 TCM Provider Survey/Key Informant Interviews and report findings • Ongoing community inventory surveillance • Ongoing monitoring of community-based co-occurring studies and evaluation for possible incorporation into evaluation • Run TCM measures and conduct data analysis for timeframe 5/1/18 – 4/30/19 and 5/1/19 - 4/30/20 • Run annual administrative measures and conduct data analysis/trending for timeframe 5/1/18 – 4/30/19 and 5/1/19 - 4/30/20 • Monitor increase in enrollment and services for cost evaluation • Generate quarterly updates • Generate final evaluation report (4/30/2021) 	<i>All Items Deferred</i>

The timeline will be updated for the 2020 Evaluation Annual Report. The evaluation team has considered the CMS suggestion about a possible extension of the evaluation timeframe. The evaluation team has weighed the benefit of an extension with the interest in a timely final report.



We propose to continue the waiver evaluation period so that the full 12-month reporting cycle of administrative data could be obtained August 2021. This would result in the final evaluation report being submitted October 31, 2021.

The evaluation team is researching suggestions to adjust for the impact of the coronavirus pandemic on health care utilization. Specifically, the State of Michigan issued a “stay-home” order effective March 23, 2020 which was not lifted until April 30, 2020. During this time, non-essential and non-emergent health care services were shut down. The evaluation team is interested in CMS feedback and recommendations regarding coronavirus related adjustments.



Methodological Limitations

The major activities in calendar years 2018 included organization of administrative data sources already available to the team as well as planning activities to implement the various surveys needed to supplement the health care claims/encounter data. The evaluation team faced issues early on regarding proposed methods to distinguish beneficiaries potentially eligible for the FME waiver regardless of enrollment as well as how to handle problematic cases (i.e. missing or incomplete data). The execution of three main surveys, beneficiary, TCM Provider and MDHHS waiver staff were a focus during 2019 as well as expanding the scope of the programming needed to report on the measures based on administrative health care data.

The evaluation team further dealt with the observation that enrollees were more geographically distributed than originally expected. The original assumption was that all potential FME enrollees would come from City of Flint residents. However, lead exposure was based on the Flint Water System delivery network of service lines which did not fully align with the city's geographic boundaries. In addition, at the start of the waiver some individuals might have already moved out of the area. This caused the team to adjust the planned approach for acquiring data from the MDHHS Data Warehouse for enrollees and potential comparison groups. The sampling strategy for the beneficiary survey also needed adjustment to incorporate a stratified method in order to accommodate this observation.

Another limitation was the inability to secure a federal Department of Education waiver to permit MDE to share education data at the individual level for linking with health care data. The evaluation team identified other data sources in response to this barrier. The evaluation team reached out to MSU faculty involved with school based public reporting. These data may provide context to the impact of the lead exposure on the educational attainment of students in the community schools however the team will be unable to quantify the impact of the waiver's offerings. The team may also utilize anecdotal data from key stakeholders of the Flint Schools and Neurodevelopmental Center for Excellence as well as related published studies to again provide context to findings. The beneficiary survey was the final data source identified as potentially useful for obtaining education related information. Several questions were designed to inquire about learning and emotional/behavioral problems for the child survey. While self-report is not without limitations, the evaluation team chose to pursue all available options.

Another limitation the evaluation team faced was the practice of individualized program data management. Several state-sponsored health related registries were not housed in MSA due to their inclusion of populations outside of Medicaid enrollees. This included both the lead screening and the MCIR data. Separate data access request and approvals were needed to acquire these data elements. Access to the lead screening data was granted during 2019 while access to MCIR data remains pending.



As the evaluation team began meeting with organizations involved in serving Flint community residents, they became aware of entities involved in FME waiver service delivery beyond what was initially identified. Thus, the evaluation was expanded to include certain data elements such as TCM provider input. Additionally, we encountered timing barriers affecting our plans to implement the beneficiary survey. The extended approval and contracting timeframe shortened the original timeline of proposed activities.

The hypotheses as written in the waiver application referenced comparing individuals enrolled in the FME waiver to others with similar BLLs. ***As of November, 2020, the evaluation team was able to evaluate BLL as a framework for establishing potential Control Group #3. Available data from the state's lead monitoring system documented the proportion having elevated levels to be low overall. The evaluation team linked available blood lead values to individuals enrolled in the waiver and found that very few individuals had reported elevated BLLs as presented in the Comparison Group Considerations section (pp. 17-19). Thus, insufficient numbers were available to conduct matching.*** The evaluation team further acknowledged that available data may not accurately reflect actual **BLLs** during the exposure period. In fact, current water testing is showing lead levels below accepted national standards, but the water system still has not yet been deemed “safe” as of January 2020. This designation cannot be granted until all affected (corroded) water service lines have been replaced. Thus, there may be ongoing exposure occurring in the population which is difficult to quantify.

The implementation of this evaluation project to date had several strengths. Gained partnerships and communications with key stakeholders to inform the evaluation were invaluable in identifying alternatives for data or methods to acquire data. Particularly, the close collaboration with the CDC funded Flint Registry project has provided supplemental information and access to interactions with a cohort of affected Flint residents. One example of the direct impact of this relationship on the evaluation operations was noted in the beneficiary survey. Members of a Flint Registry Parent Advisory Group provided information on the willingness and ability to complete web-based surveys which caused the evaluation team to reconsider planned survey methods. As the Wave 1 survey had not yet been distributed, an online version was included and positively received by those invited to participate.

Preliminary Results

Results presented as part of this interim evaluation include data available to the evaluation team and summarized as of December 31, 2019 based on evaluation activities occurring between January 2018 – December 2019. The findings are presented by Evaluation Domain and relevant hypotheses. Where available, administrative health care claims or enrollment data as far back as **May 2013** was obtained in order to provide estimates **for the baseline year (T1) that reflected the period 12 months prior to the water switch. The following tables have been relabeled to more clearly reflect the three timeframes presented on pages 4-5.** Because of time needed to allow claims processing to occur, the most recent utilization data available for this interim report ends April 2019.

Comparison Group Considerations

In many of the measures identified for the hypotheses, they were worded in such a manner to propose that FME enrollees will have better access *compared with others with similar levels of lead exposure*. The reference to others reflects on the selection of an appropriate comparison group. As described in the Target and Comparison Populations section, each of the four potential comparison populations suffered from limitations. The most significant of which is the inability to accurately quantify the level of lead exposure from what is most frequently a one-time blood draw. **As described in the Target Population section, the evaluation team chose to establish Comparison Group #5, Beneficiaries with similar individual and neighborhood characteristics at the census tract level.**

The final selection of the comparison community has been decided since this interim report was submitted in January 2020. The K-means analysis confirmed that Saginaw County would be a suitable option for Comparison Group #5 (for details see Appendix 7). Upon identification of the comparison community, the MDHHS Data Warehouse was accessed for claims/encounter data for all Medicaid enrollees residing in Saginaw County since May 2013 through April 2020. History of comorbidity and/or similar census-tract level social/economic background were adjusted when appropriate in regression models. Direct comparisons to control estimates will be provided **in the 2020 Evaluation Annual Report.**

Potentially Eligible Waiver Population Characteristics

The expansion **enrollment** date was 5/9/2016. Residency in the City of Flint or Genesee County was not required for enrollment into the FME waiver. **The State of Michigan became aware that** initial methods to identify potentially eligible individuals using a list of seven Flint zip codes was incomplete when compared to the City's water service distribution network. Therefore, they added four zip codes representing areas that existed outside of the City of Flint's



geographic boundaries yet were exposed to the affected water. This full list of eleven zip codes represented the Flint Water Service Area (FWSA) and was used to identify potentially eligible individuals. The eleven zip codes were all contained within the geographic boundaries of Genesee County. The evaluation team also noted potentially eligible individuals relocating to other geographic areas since the water crisis. Based on data contained in enrollment records, individuals relocated since the water switch outside of the FWSA and even outside of Genesee County to elsewhere in the state. ***We could not identify all potentially eligible individuals who relocated outside Genesee County and we used the FME Waiver benefit plan enrollment indicator to identify those who relocated.*** We theorized that individuals who relocated may have had different levels of resources than those who remained in the same location. This will be empirically tested upon acquisition of all the data. ***The history of Medicaid enrollment will be used as a proxy for resources and compared between those who relocated and those who did not.***

We initially employed a two-step method to independently construct the population of “eligible” individuals. The first step was to assign a flag to indicate potential eligibility using available general Medicaid enrollment files back to the date of the water switch, April 25, 2014. Individuals were deemed “potentially” eligible for the FME Waiver by having at least one month of Genesee County residence in their Medicaid enrollment history files back to the water switch date. Individuals did not have to meet any continuous enrollment criteria and any county match for any duration of time was taken as sufficient evidence of exposure. We coupled this information with Modified Adjusted Gross Income (MAGI) information collected during the Medicaid determination process to confirm individuals would qualify per the FPL limitations. We did not believe that all of Genesee County would be eligible and initially selected these individuals with the belief that they may serve as a comparison group.

However, enrollment into the FME Waiver did not require residential history at one of the eleven zip codes. Individuals would be eligible to enroll if they could document exposure to the water source despite living outside the FWSA. This determination could not be made using existing administrative data. In fact, the evaluation team identified individuals enrolled in the FME Waiver through administrative data that had no history of having lived at one of the eleven zip codes or even in Genesee County. This could occur when an individual resided outside the geographic boundaries but attended school, work, or spent time in the eleven zip code FWSA. Individuals meeting the requirement for documented exposure without geographic residence formed a second group of “eligible” individuals. These individuals were classified as eligible since they were in fact, identified as already enrolled. Specifically, they had the appropriate FME Waiver benefit plan identifier assigned by Michigan Medicaid.

A limitation of this approach is that the evaluation team was unable to determine the true number of potentially eligible individuals that may have been exposed to the water but never presented to the State of Michigan for Medicaid coverage. This limitation would be expected



to have a greater impact on the ability to determine the FME Waiver’s impact on those who were at the increased FPL thresholds. Individuals at these higher levels may have history trying to access Medicaid coverage in the past and been denied due to income. Despite the public information campaigns of the expanded coverage options, these individuals may have assumed they would still be denied. Another factor potentially impacting enrollment for those at higher FPL may be that individuals at the higher levels were not interested in Medicaid coverage through the waiver for a variety of reasons including having other forms of insurance and/or perceived stigma of being enrolled in Medicaid. One option that the evaluation team will use to determine the relative proportion of the higher FPL in the enrolled cohort is to use the enrollees’ census data and the non-enrollees’ census data to compare population characteristics such as FPL levels.

We identified individuals officially enrolled in the waiver using a combination of Modified Adjusted Gross Income (MAGI) and Medicaid Benefit Plan codes available through the MDHHS Health Services Data Warehouse. Enrollees were identified by a MAGI code beginning with “F” along with a current benefit plan of “TCMF”. Pregnant women eligible and enrolled in the Waiver were identified through a combination of eligible MAGI codes along with Medicaid Scope and Coverage codes and claims related to live births. ***The prenatal care related claims with a birth record combination was found to be the most accurate method to identify pregnant women.*** These coding algorithms were reviewed with MDHHS colleagues for accuracy.

Using Medicaid eligibility and FME waiver enrollment data contained in the MDHHS Health Services Data Warehouse, Table 7 described the potentially covered population and selected data cleaning steps performed on the original cohort. ***We restrict our presentation to the 12-month period immediately before the ability to enroll in the FME Waiver and then annually after FME Waiver implementation. The 2020 Evaluation Annual Report will include the additional year of information through April 2020.*** Table 7 further quantified the number of individuals being dropped from analyses due to potentially problematic/erroneous data. This process is also displayed in Figure 2.



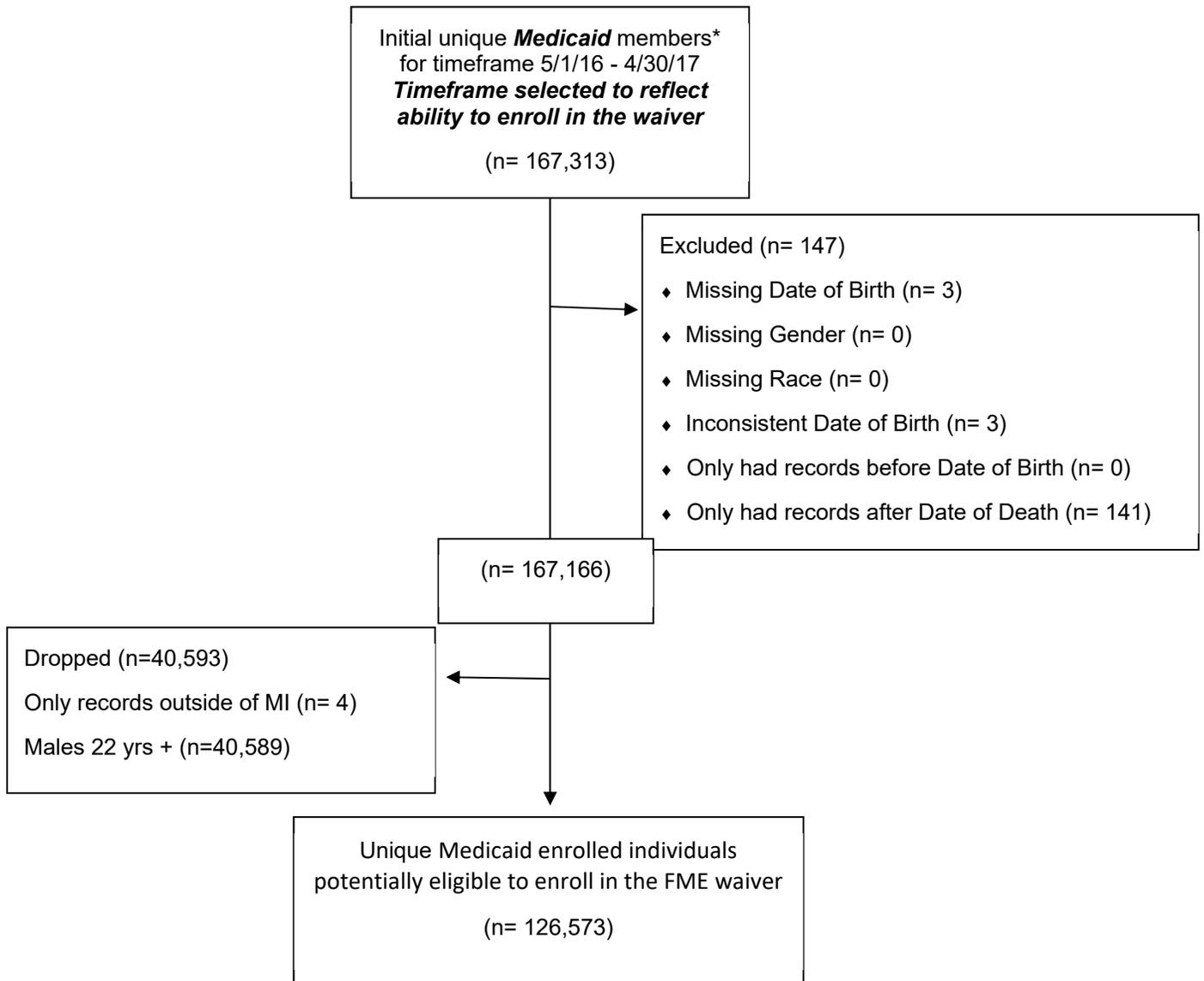
Table 7: Potentially covered population identified* for 12 months preceding and three years following FME Waiver Start (5/2016)

Timeframe	T2: Post Water Switch and Pre FME enrollment	T3: Post Water Switch and Post FME enrollment		
	5/1/15—4/30/16	5/1/16—4/30/17	5/1/17—4/30/18	5/1/18—4/30/19
Initial unique potentially eligible members identified based on Genesee county residence	169,713	167,313	168,958	166,662
Missing date of birth	8	3	0	0
Missing gender	0	0	0	0
Missing race	0	0	0	0
Inconsistent year of birth	20	2	0	0
Inconsistent month of birth	4	1	0	0
Only had eligibility records before recorded date of birth	1	0	5	0
Only had eligibility records after recorded date of death	177	141	166	188
Only had eligibility records outside Michigan	7	4	37	19
Males age 22 and older as of 10/1 of each year	40,746	40,589	41,653	40,834
Total potentially eligible members retained	128,750	126,573	127,097	125,621
Total Genesee County Population	408,901	407,673	406,892	406,111

*Potentially covered population includes anyone residing in Genesee County, meeting FME waiver age and pregnancy criteria only plus anyone else formally enrolled in the FME waiver.



Figure 2: Sample eligibility cleaning process applied



*Potentially covered population includes anyone residing in Genesee County meeting FME waiver age and pregnancy criteria only plus anyone else formally enrolled in the FME waiver.

The potential eligible cohort definition used by the evaluation team exceeded the number estimated by the State of Michigan in the FME waiver application (n=15,000 newly eligible plus n=30,000 existing Medicaid beneficiaries). This was because the evaluation team was originally interested in using others in a similar geographic region as potential controls **so the denominator was initially suggested to include Genesee County residence rather than only the eleven zip codes in the FWSA.**



Table 8 reflects the enrollment that might be expected based on the estimates of people that could be specifically tied to the target eleven zip codes included in the FWSA. The potential denominator decreased from the county-wide area estimate (n=126,572) to the eleven zip code area estimate (n=79,337). Enrollment based on the eleven zip code area is approximately 38% (29,939/79,337). However, we observed enrollment of individuals that we could not link to the target eleven zip codes so total enrollment for the first year was 33,517. Despite being unable to link these additional individuals to residence in the eleven zip codes, we documented the bulk of waiver enrollment, nearly 90% (29,939/33,517) did come from the FWSA. Those not in the target zip codes may have differential access to other, non-Medicaid community formal and informal supports. Sub-group analyses will attempt to quantify differences in outcome measures for these two categories of enrollees (in FWSA vs. out of FWSA). Table 8 displayed the socio-demographic characteristics of the potentially eligible cohorts, those in Genesee County, those residing in the FWSA and those who enrolled in the FME waiver. Minimal variation was observed between the two timeframes (pre-post FME start) for population characteristics of the potentially eligible cohort residing in Genesee County. As we restricted to the FWSA geographic region which included the City of Flint, little variation was noted among the age and gender proportions. However, the proportion of non-Hispanic, African American beneficiaries identified as potentially eligible increased nearly 10% with a corresponding decrease noted in the number of non-Hispanic, White beneficiaries. This observation was consistent with the racial make-up of the City of Flint.



Table 8: Population characteristics of Potentially Eligible before and after May 1, 2016 corresponding to T2 and T3.

	Medicaid Eligible in Genesee County plus Statewide FME Waiver Enrollees		Medicaid Eligible in Eleven Zip Code FWSA		FME Waiver Enrollees (5/1/16 – 4/30/17)	
	T2: Post Water Switch and Pre FME Waiver 5/1/15—4/30/16	T3: Post Water Switch and Post FME Waiver 5/1/16—4/30/17	T2: Post Water Switch and Pre FME Waiver 5/1/15—4/3/16	T3: Post Water Switch and Post FME Waiver 5/1/16—4/30/17	T3: Total	T3: FWSA Subgroup
Count of unique Medicaid beneficiaries	N=128,750	N=126,572	N=80,652	N=79,337	N=33,517	N=29,939
Age (Years, as of October 1 of each year)						
0-6	22.0%	22.1%	22.6%	22.5%	39.8%	39.5%
7-16	25.0%	24.9%	24.2%	24.4%	41.2%	41.7%
17-21	11.6%	11.4%	11.5%	11.1%	14.9%	14.7%
22-64	37.8%	37.9%	38.6%	38.7%	4.1%	4.0%
65+	3.5%	3.6%	3.1%	3.2%	(22+)*	n/a
Gender						
Male	29.6%	29.4%	29.3%	29.1%	47.9%	48.2%
Female	70.4%	70.6%	70.7%	70.9%	52.1%	51.8%
Race/Ethnicity						
non-Hispanic white	55.2%	55.0%	43.3%	43.2%	31.9%	29.5%
non-Hispanic black	34.6%	34.8%	47.6%	47.8%	59.6%	62.4%
Hispanic/Other	4.1%	4.2%	4.0%	4.0%	4.3%	4.2%
Unknown	6.1%	6.0%	5.1%	5.0%	4.3%	4.0%
Residence Category						
Only Genesee County	55.2%	55.0%	99.0%	98.3%	90.7%	95.8%
Partial Genesee County	34.6%	34.8%	1.0%	1.7%	4.2%	4.1%
Never Genesee County	4.1%	4.2%	0.0%	0.1%	5.1%	0.1%
FME Waiver Enrollment						
Proportion having any FME enrollment	n/a	26.5%	n/a	37.7%	100%	100%
Pregnancy Indicator	2.6%	3.0%	2.8%	3.2%	4.8%	4.6%
Federal Poverty Level Category (% FPL)						
FPL 0 - 99%	81.5%	79.1%	83.9%	81.1%	76.9%	77.6%
FPL 100 - 199%	17.3%	19.3%	15.2%	17.4%	19.8%	19.4%
FPL 200 - 299%	1.2%	1.4%	0.8%	1.2%	2.6%	2.4%
FPL 300% +	0.1%	0.2%	0.1%	0.2%	0.6%	0.6%

*Categories collapsed due to small cell sizes



Table 9 shows some sociodemographic changes when reviewing the most recent enrollment year (5/1/18 – 4/30/19). Turning attention to the characteristics of the FME enrolled population, we observed the proportion of the younger age categories substantially increased as designed by the waiver criteria. The gender distribution remained relatively unchanged. Another 10% increase in the non-Hispanic, African American segment of FME waiver enrollees was observed. Ten percent of those enrolled in FME resided outside of Genesee County at some point during their coverage. This highlighted the importance of the water exposure screening criteria allowing for individuals to access the services even if they did not live in the City of Flint. FME also appeared to be successful in reaching out to pregnant women for coverage. According to enrollment data, it appeared the FME was having success at recruiting and covering individuals at the higher income levels permitted under the waiver.



Table 9: Population characteristics of Potentially Eligible before May 1, 2016 corresponding to T2 and after 5/1/18 corresponding to T3.

	Medicaid Eligible in Genesee County plus Statewide FME Waiver Enrollees		Medicaid Eligible in Eleven Zip Code FWSA		FME Waiver Enrollees (5/1/18 – 4/30/19)	
	T2: Post Water Switch and Pre FME Waiver 5/1/15–4/30/16	T3: Post Water Switch and Post FME Waiver 5/1/18–4/30/19	T2: Post Water Switch and Pre FME Waiver 5/1/15–4/3/16	T3: Post Water Switch and Post FME Waiver 5/1/18–4/30/19	T3: Total	T3: FWSA Subgroup
Count of unique Medicaid beneficiaries	N=128,750	N=125,621	N=80,652	N=77,772	N=31,801	N=26,131
Age (Years, as of October 1 of each year)						
0-6	22.0%	21.9%	22.6%	22.2%	35.4%	35.0%
7-16	25.0%	25.3%	24.2%	24.7%	45.6%	46.2%
17-21	11.6%	11.3%	11.5%	11.0%	16.3%	16.3%
22+	41.3%	41.5%	41.7%	42.2%	2.8%	2.5%
Gender						
Male	29.6%	29.5%	29.3%	29.1%	49.2%	49.5%
Female	70.4%	70.5%	70.7%	70.9%	50.8%	50.5%
Race/Ethnicity						
non-Hispanic white	55.2%	54.4%	43.3%	42.6%	33.1%	29.0%
non-Hispanic black	34.6%	35.3%	47.6%	48.4%	58.3%	63.0%
Hispanic/Other	4.1%	4.4%	4.0%	4.2%	4.3%	4.2%
Unknown	6.1%	5.9%	5.1%	4.9%	4.3%	3.8%
Residence Category						
Only Genesee County	55.2%	96.8%	99.0%	98.8%	87.4%	96.4%
Partial Genesee County	34.6%	0.9%	1.0%	1.2%	3.5%	3.5%
Never Genesee County	4.1%	2.3%	0.0%	0.0%	9.0%	0.1%
FME Waiver Enrollment						
Proportion having any FME enrollment	n/a	25.3%	n/a	33.6%	100.0%	100.0%
Pregnancy Indicator	2.6%	2.9%	2.8%	2.3%	3.3%	3.0%
Federal Poverty Level Category (% FPL)						
FPL 0 - 99%	81.5%	79.4%	83.9%	81.5%	76.1%	76.7%
FPL 100 - 199%	17.3%	18.7%	15.2%	16.7%	19.5%	19.1%
FPL 200 - 299%	1.2%	1.6%	0.8%	1.5%	3.4%	3.3%
FPL 300% +	0.1%	0.3%	0.1%	0.3%	1.0%	0.9%



FME Waiver Enrollment

Table 10 displays the change in socio-demographic characteristics among those who were enrolled in the FME waiver regardless of residence since the start of the FME waiver from May 2016 to April 2019. An increasing number of beneficiaries who enrolled in FME now reside outside Genesee county. The observation of a decline in overall enrollment since waiver approval confirmed the pattern anticipated by Medical Services Administration (MSA) informants. The waiver authorized individuals at higher FPL to qualify for the benefit and for those exceeding the 400% threshold, to buy into the program in order to secure access to TCM. The use by individuals at these higher income thresholds continues to be small.

Over the three years, a total of 40,543 unique beneficiaries had at least one FME enrollment month, among whom 25,641 (63%) enrolled for all three years. Approximately 6%, (n=2,486) of unique beneficiaries newly enrolled during the 2018/19 timeframe.



Table 10: Total Medicaid statewide FME waiver enrollees from May 1, 2016 to April 30, 2019

	FME Waiver Enrollee (T3: 5/1/16-4/30/17)	FME Waiver Enrollee (T3: 5/1/17-4/30/18)	FME Waiver Enrollee (T3: 5/1/18-4/30/19)
Count of unique Medicaid beneficiaries	N=33,516	N=33,921	N=31,801
Age (Years, as of October 1 of each year)			
0-6	39.8%	38.0%	35.4%
7-16	41.2%	42.6%	45.6%
17-21	14.9%	16.1%	16.3%
22+	4.1%	3.3%	2.7%
Gender			
Male	47.9%	48.6%	49.2%
Female	52.1%	51.4%	50.8%
Race/Ethnicity			
non-Hispanic white	31.9%	32.8%	33.1%
non-Hispanic black	59.6%	59.0%	58.4%
Hispanic/Other	4.3%	4.3%	4.3%
Unknown	4.3%	4.0%	4.3%
Residence Category			
Only Genesee County	90.7%	88.6%	87.4%
Partial Genesee County	4.2%	4.0%	3.5%
Never Genesee County	5.1%	7.3%	9.0%
Federal Poverty Level Category (% FPL)			
FPL 0 - 99%	75.6%	76.0%	76.1%
FPL 100 - 199%	20.9%	20.0%	19.5%
FPL 200 - 299%	2.8%	3.2%	3.4%
FPL 300% +	0.7%	0.8%	1.0%



Domain 1: Access to Care

The main hypothesis for Domain 1 focused on access to care: *“Enrollees will access services to identify and address physical or behavioral health issues associated with lead exposure at a rate higher than others with similar levels of lead exposure.”* Nine specific sub-hypotheses were identified to provide measures of access for both targeted populations, children and pregnant women. Sub-hypotheses 1.1 through 1.5 were chosen for their applicability to a pediatric population while items 1.5, 1.6 and 1.7 were relevant for pregnant women. These seven sub-hypotheses used administrative health care claims for evaluation. Baseline information was calculated for the **T1** pre-water switch timeframe (May 2013 – April 2014) through the most recent completed available data year (May 2018 – April 2019). The last two sub-hypotheses acquired the necessary data through the beneficiary survey process.

Sub-hypotheses 1.1: Improved Access to Care

- 1.1: *A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.*

The Well-Child Check HEDIS Measure was defined in terms of three age groups. The first metric included the percentage of children 15 months old who had the recommended number of well-child visits with a PCP during their first 15 months of life. The second metric focused on children 3-6 years of age having a well-child visit during the year. The last metric reported on adolescents from 12-21 years of age.

Table 11 reflects the proportion of continuously **enrolled** children who received at least one well-child check. The evaluation team restricted to children that were continuously enrolled **during a 12 month reporting period** to ensure that complete claims/encounter data was available through the Medicaid Health Services Data Warehouse when assessing service use. Imposing the requirement for continuous **enrollment** retained a majority (>80%) of all possible beneficiaries for the age group up to 15 months. The retention of beneficiaries for reporting increased to at least 90% for both older groups. When the team compared the reporting rates between those who were ever enrolled (i.e. not continuously enrolled) with those who were continuously enrolled, the results were approximately within five percent with the “ever enrolled” consistently being lower. This was not unexpected as there would be no way to document health services delivered and paid for by other insurance or programs during periods of Medicaid ineligibility. ***These results will be compared to the experience of the Saginaw County comparison community and reported in the 2020 Evaluation Annual Report.***



Table 11. Well-Child Visits for all Age Groups: 5/1/2013 – 4/30/19

	T1: 5/1/2013— 4/30/2014	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value for trend*
Well-Child Visits in the First 15 Months of Life							
N	N=4328	N=4274	N=3617	N=1072	N=1538	N=887	
Had any visits	2781 ^a (64.3%)	4072 (95.3%)	3483 (96.3%)	1046 (97.6%)	1500 (97.5%)	867 (97.7%)	<0.01
Well-Child Visits at Age 3, 4, 5, and 6 Years							
N	N=16143	N=15413	N=14714	N=5736	N=6280	N=6158	
Had any visits	11978 (74.2%)	11413 (74.0%)	10484 (71.3%)	4059 (70.8%)	4554 (72.5%)	4453 (72.3%)	<0.01
Adolescent Well-Care Visits Age 12 -21 years.							
N	N=29090	N=30122	N=28931	N=9010	N=10015	N=10051	
Had any visits	11458 (39.4%)	12120 (40.2%)	12068 (41.7%)	3736 (41.5%)	4141 (41.3%)	4252 (42.3%)	<0.01

* P-value for well-child visits in the first 15 months of life is based on logistic regression with cluster robust standard error clustering children within zip codes; p-values for well-child visits at age 3, 4, 5 and 6 years and adolescent well-care visits for age 12-21 years are based on random effects logistic regression with a random intercept at the beneficiary level and robust standard errors.

a. Only 12 months of history (rather than full 15 months) available for T1 analysis thus rate adversely impacted by incomplete data

Sub-hypotheses 1.2: Improved Access to Care

- 1.2: *A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures.*

It is known that lead is a neurotoxin and that children exposed to high levels of lead may experience poor developmental and behavioral health. Thus, developmental and behavioral screening is necessary to assess problems early for timely treatment to mitigate poor outcomes. Thus, to address sub-hypotheses 1.2, observed rates based on administrative claims data for any number of developmental and behavioral screening visits in the first three years of life are presented in Table 12. As with 1.1, rates reported are based on continuous **enrollment during the 12-month reporting period** from 5/1/2013 to 4/30/2019 for children age 1, 2 or 3 years old. For 2013-2014, before the water crisis, 7% of children had developmental screening visits. This rate increased to 19.8% during the first year of the water crisis, 2014 – 2015 and 25% in 2015-2016 before the waiver was administered. The proportion having at least one developmental screening visit for those enrolled in the waiver continues to increase over time.



Table 12. Developmental/Behavioral Screening visits in the First Three Years of Life: 5/1/2013-4/30/2019

	T1: 5/1/2013— 4/30/2014	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value for trend*
Developmental screening in the first 3 years of life							
N	N=11782	N=11936	N=11777	N=5646	N=5621	N=4297	
Had any visits	829 (7.0%)	2358 (19.8%)	2961 (25.1%)	1784 (31.6%)	2053 (36.5%)	1775 (41.3%)	<0.01

*P-value is based on random effects logistic regression with a random intercept at the beneficiary level and robust standard errors.

Sub-hypotheses 1.3: Improved Access to Care

- 1.3: *A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures.*

Examining lead screening using administrative claims and lab data for children continuously **enrolled for the twelve-month reporting period** from 5/1/2013-4/30/2019 showed steady increases for all years until 2018-2019. In 2013-2014 reported claims revealed a lead screening rate of 35.2%. In the year of the water crisis, 2014-2015, screening jumped to 70.6% and 72.2% in 2015-2016. Screening in the first year of the waiver implementation (2016-2017) was 81.3% for waiver enrollees. This trend leveled off most recently (2018-2019) to 71.3% for waiver enrollees.

Table 13. Lead Screening in Children using claims or lab data. 5/1/2013-4/30/19.

	T1: 5/1/2013— 4/30/2014	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value*
N	N=3624	N=3836	N=3774	N=1849	N=1824	N=1778	
Had any BLL testing (N, %)	1274 (35.2%)	2710 (70.6%)	2723 (72.2%)	1503 (81.3%)	1430 (78.4%)	1268 (71.3%)	<0.01

*P-value is based on logistic regression with cluster robust standard error clustering children within zip codes.

Sub-hypotheses 1.4: Improved Access to Care

- 1.4: *A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures.*

For some children, high BLL can be elevated and given the recent elevated lead content in Flint supplied water re-testing for those children is critical. Affected children documented to have elevated blood lead values need to be re-tested to monitor impacts of treatment. In 2013-2014,

BLL re-testing was 8.3% before the water crisis and 11.9% during the water crisis. For the year the waiver was implemented, 32.5% for enrollees needing to be re-tested were re-screened. Rates were similar in 2017-18 at 34.3% and increased to 42.5% for the most recent reporting year (2018-2019).

Table 14. Blood lead level re-testing with children with elevated BLL, 5/1/2013-4/30/19.

	T1: 5/1/2013— 4/30/2014	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value*
N	N=205	N=226	N=351	N=246	N=143	N=80	
Had any BLL retesting** (N, %)	17 (8.3%)	27 (11.9%)	83 (23.6%)	80 (32.5%)	49 (34.3%)	34 (42.5%)	<0.01

*P-value is based on random effects logistic regression with a random intercept at the beneficiary level and robust standard errors.

Sub-hypotheses 1.5: Improved Access to Care

- 1.5: *Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.*

Prenatal and postpartum care is essential especially during environmental crises whereby the mother and baby may be at physical (lead exposure, miscarriage) and behavioral risks (toxic stress, postpartum depression). To address sub-hypothesis 1.5 claims data was examined to assess timeliness of prenatal care according to accepted HEDIS specifications (e.g., percentage of deliveries that received a prenatal care visit in the first trimester, on the enrollment start date or within 42 days of enrollment in the organization). HEDIS specifications for identifying prenatal and postpartum care require the practitioner type to be “an OB/GYN or other prenatal care practitioner or PCP”. At times, the administrative claims data does not fully document the billing and rendering provider information. Therefore, the evaluation team chose to present three algorithms for identifying prenatal and postpartum care. In algorithm #1, we used only the procedure (CPT) and diagnosis (DX) codes related to prenatal care (bundled to stand alone visits); in algorithm #2, we considered either the CPT/DX codes or the provider taxonomy codes to capture the most records; and in algorithm #3, we used both the CPT/DX codes and the provider taxonomy codes, which apply the most stringent criteria, but are subject to missing provider information. Table 15 shows that although there was a steady decline in the number of births, the proportion of timely prenatal and postpartum care remained relatively high using the first two algorithms. ***Because of the look-back period required for these perinatal care measures, T2 does reflect to some degree T1 activity. Claims data prior to 5/1/13 were not acquired so a separate reporting of T1 is not available.***



Table 15. Timeliness of Prenatal Care 5/1/2014 - 4/30/19

	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value**
N	2,871	2,567	1070	762	432	
Algorithm #1 (CPT/DX)						
Had prenatal care visit (N, %)	1839 (64.1%)	1848 (72.0%)	762 (71.2%)	535 (70.2%)	299 (69.2%)	<0.01
Algorithm #2 (CPT/DX or taxonomy)						
Had prenatal care visit (N, %)	2043 (71.2%)	1983 (77.1%)	812 (75.9%)	573 (75.2%)	333 (77.1%)	<0.01
Algorithm #3 (CPT/DX and taxonomy)						
Had prenatal care visit (N, %)	1750 (61.0%)	1613 (62.8%)	353 (33.0%)	271 (35.6%)	165 (38.2%)	**

*Due to additional requirements for prenatal and postpartum care measures, the sample size in Tables 14 and 15 are slightly different. **Algorithm #3 led to decreasing trend due to lack of taxonomy codes in later years of claims data. P-values are based on logistic regressions with cluster robust standard error clustering women within zip codes.

Sub-hypotheses 1.6: Improved Access to Care

- 1.6: *A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures.*

Lead screening for pregnant women is important to mitigate adverse birth outcomes associated with the exposure to high levels. This sub-hypothesis reported lead screening in pregnant women having a live birth. Prior to the water crisis, 5/1/2013-4/30/2014, very few data points were identified as evidence for this screening. However, in 2015-2016, during the time when pregnant women were mostly likely exposed to lead and the crisis was public, lead screening increased to 10.2% of the **Medicaid continuously enrolled** beneficiaries. These rates continued to increase even higher for women continuously enrolled in the FME waiver.

Table 16. Lead Screening in pregnant women with live birth using claims and lab data, 5/1/2013-4/30/19

	T1: 5/1/2013— 4/30/2014	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value**
N	N=3354	N=3220	N=2938	N=1119	N=866	N=545	
Had any BLL testing** (N, %)	2 (0.1%)	7 (0.2%)	300 (10.2%)	780 (69.7%)	638 (73.7%)	428 (78.5%)	<0.01

*Due to additional requirements for prenatal and postpartum care measures, the sample size in Tables 14 and 15 are slightly different. **P-values are based on logistic regressions with cluster robust standard error clustering women within zip codes in which the first two years of data were excluded due to incompleteness. P-value still <0.01 if the 2015 data were also excluded.

Sub-hypotheses 1.7: Improved Access to Care

- 1.7: *A greater proportion of enrollees will participate with home visiting services compared to others with similar lead levels.*

In Michigan, enhanced prenatal services are available through a home visiting service called the Maternal Infant Health Program (MIHP). This program is intended to address high risk pregnancies with an increase of specialized services. The program may also offer transportation and birthing classes along with professional visits. Since the interest in this measure was to evaluate active program engagement, the team restricted on professional visits. Administrative health care data assessing for MIHP services was reviewed. Prior to the water crisis, 27.4% of live births showed evidence of MIHP participation. This rate was essentially unchanged during the two years of the initial water crisis. Waiver enrollees appeared to have a slight increase in participation followed by a downward trend. Reasons for this decline are not well-understood. The evaluation team plans to reach out to MIHP program staff to learn whether larger scale program participation changes have been documented. The results of those discussions will inform the final evaluation report.

Table 17. MIHP participation with Medicaid deliveries of live births (5/1/2013-4/30/2019).

	T1: 5/1/2013— 4/30/2014	T2: 5/1/2014— 4/30/2015	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019	P-value*
N	N=3354	N=3220	N=2938	N=1119	N=866	N=545	
Had any MIHP (prof) visit (N, %)	918 (27.4%)	878 (27.3%)	835 (28.4%)	338 (30.2%)	234 (27.0%)	121 (22.2%)	0.842

*P-value is based on logistic regressions with cluster robust standard error clustering deliveries within zip codes in which the last year’s data were excluded due to incompleteness. Including the last year’s data did not change the significance.

Sub-hypotheses 1.8: Improved Access to Care

The beneficiary survey was the primary vehicle to obtain data regarding enrollee rating of the success of the waiver in improving their health care as specified in sub-hypotheses 1.8 and 1.9. For this interim report, the first wave was completed and analyzed. Refer to Appendix 4 for the full report. The second wave **data collection period concluded in June 2020. The results will be incorporated into the 2020 Evaluation Annual Report.**

- 1.8: *Enrollees will attest to improved access to health care as a result of the expanded coverage.*

Although most respondents reported that they were already enrolled in Medicaid for both the child (85%) and adult (80%) survey participants, over 400 individuals presumably experienced this as a new form of coverage. Table 18 shows the proportion of respondents selecting each answer option.



Table 18. Reasons for Enrollment in Medicaid

Question	Child N=2356	Adult N=225	Total N=2581
What were the reasons you enrolled (your child) in the Flint Medicaid Waiver? <i>Check all that apply</i>	N (%)	N (%)	N (%)
Already enrolled in Medicaid	1994 (84.5)	179 (79.6)	2173 (84.2)
To get health services	574 (24.4)	70 (31.1)	644 (25.0)
For targeted case management/family supports services	247 (10.5)	20 (8.9)	267 (10.3)
Help with behavioral or emotional issues	236 (10.0)	25 (11.1)	261 (10.1)
To lower health costs	162 (6.9)	16 (7.1)	178 (6.9)
Other reason	117 (5.0)	8 (3.6)	125 (4.8)

Two questions were posed to respondents asking about the ease of obtaining health care services related to enrollment in the waiver. The first question asked generally about the level of difficulty obtaining services. A follow-up question specifically asked respondents whether the level of difficulty had decreased.

When asked about the ease of getting health care since enrollment in the Medicaid program, more than half of all survey participants (53%) reported that it was *easy* and an additional 29% reported it was *fairly easy*. Respondents answering on behalf of children were more likely to rate getting health care since enrollment *easy* compared to adult respondents (Table 19).

Table 19: General Ease of Getting Health Care

Question	Child N=2330	Adult N=221	Total Respondents N=2551
Since enrolling in the Flint Medicaid waiver, how easy was it to get the medical care, tests, or treatment you (your child) needed?	N (%)	N (%)	N (%)
Easy	1269 (54.4)	94 (42.5)	1363 (53.4)
Fairly Easy	672(28.8)	80 (36.2)	752 (29.5)
Not Easy, Not Difficult	306 (13.1)	38 (17.2)	344 (13.5)
Difficult	68 (2.9)	6 (2.7)	74 (2.9)
Very Difficult	15 (0.6)	3 (1.4)	18 (0.7)



More than half (60%) of both survey cohorts (child and adult) *strongly agreed* or *agreed* with the statement that the Flint Medicaid waiver made it easier to get the health care they or their child needed. Results for these items are displayed in Table 20.

Table 20. Specific Flint Medicaid Waiver Makes it Easier to Get Health Care

Question	Child N=2337	Adult N=222	Total N=2559
Being in the Flint Medicaid waiver made it easier to get the health care I (my child) needed.	N (%)	N (%)	N (%)
Strongly Agree	550 (23.5)	52 (23.4)	601 (23.5)
Agree	782 (33.5)	81 (36.5)	863 (33.7)
Neutral	855 (36.6)	74 (33.3)	930 (36.3)
Disagree	106 (4.5)	10 (4.5)	116 (4.5)
Strongly Disagree	44 (1.9)	5 (2.2)	49 (1.9)

Sub-hypotheses 1.9: Improved Access to Care

- 1.9: *Enrollees will report improved satisfaction with their ability to access health care as a result of the expanded coverage.*

Beyond simply offering the opportunity for expanded access and coverage, another aspect related to uptake was the overall satisfaction enrollees reported with their waiver experiences. The expanded coverage was offered through the health plans that operate in the affected geographic region. Thus, waiver participants had the benefit of existing health plan relationships with a variety of health care and community providers.

Several questions were asked on the survey targeting specific aspects of the waiver coverage. A general rating question was asked of participants. Respondents to the child survey rated the coverage slightly better than the adult survey respondents (7.4 vs. 6.9) as displayed in Table 21.

Table 21. Satisfaction with Flint Medicaid Waiver

Question	Child N=2312 Mean (SD)	Adult N=224 Mean (SD)	Total N=2536 Mean (SD)
Choosing a number from 0 to 10, where 0 is the worst and 10 the best, what number would you use to rate your overall Flint Medicaid waiver experience?	7.4 (3.1)	6.9 (2.3)	7.4 (3.0)



An additional satisfaction question targeted health care providers generally. Regarding health care providers working in the enrollee’s best interest, approximately 64% *strongly agreed* or *agreed* with the statement (Table 22).

Table 22. Satisfaction with Health Care Providers Working in Enrollee Interest

Question	Child N=2333	Adult N=222	Total N=2555
Since enrolling in the Flint Medicaid waiver, I feel that the health care providers are working in my (child’s) best interest.	N (%)	N (%)	N (%)
Strongly Agree	590 (25.3)	49 (22.1)	639 (25.0)
Agree	910 (39.0)	89 (40.1)	999 (39.1)
Neutral	704 (30.2)	67 (30.2)	771 (30.2)
Disagree	98 (4.2)	11 (5.0)	109 (4.3)
Strongly Disagree	31 (1.3)	6 (2.7)	37 (1.4)

Sub-hypotheses 1.8-1.9: Improved Access to Care – Wave 1 to Wave 2 Variation

Wave 2 of the enrollee survey **has concluded**. For those questions included in both waves, the evaluation team will explore changes over time between the two waves. Thus, the results reported here are *preliminary* and only represented one-third of the Wave 1 participant cohort. They are presented only to provide some indication of patterns that have emerged to date. **Tables 23 and 24 will be updated with the complete Wave 2 data and presented in the 2020 Evaluation Annual Report.**

Between Wave 1 and Wave 2, the proportion of available respondents acknowledging the waiver made it *easy* to get care increased. The shift appeared to be a result of the decline in those that originally reported having a neutral opinion.



Table 23: General Ease of Getting Health Care

Question	Child		Adult		Total Respondents	
	Wave 1 N =2330	Wave 2 N=786	Wave 1 N=221	Wave 2 N=64	Wave 1 N=2551	Wave 2 N=850
Since enrolling in the Flint Medicaid waiver, how easy was it to get the medical care, tests, or treatment you/your child needed?	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Easy	1269 (54.4)	492 (62.6)	94 (42.5)	20 (31.3)	1363 (53.4)	512 (60.2)
Fairly Easy	672 (28.8)	226 (28.8)	80 (36.2)	28 (43.8)	752 (29.5)	254 (29.9)
Not Easy, Not Difficult	306 (13.1)	48 (6.1)	38 (17.2)	8 (12.5)	344 (13.5)	56 (6.6)
Difficult	68 (2.9)	17 (2.2)	6 (2.7)	7 (10.9)	74 (2.9)	24 (2.8)
Very Difficult	15 (0.6)	3 (0.4)	3 (1.4)	1 (1.6)	18 (0.7)	4 (0.5)

However, essentially no variation has been observed thus far in the overall satisfaction rating between the waves.

Table 24. Satisfaction with Flint Medicaid Waiver

Question	Child Mean (SD)		Adult Mean (SD)		Total Mean (SD)	
	Wave 1 N=2312	Wave 2 N=770	Wave 1 N=224	Wave 2 N=64	Wave 1 N=2536	Wave 2 N=834
Choosing a number from 0 to 10, where 0 is the worst and 10 the best, what number would you use to rate your overall Flint Medicaid waiver experience?	7.4 (3.1)	7.5 (2.4)	6.9 (2.3)	6.9 (2.1)	7.4 (3.0)	7.3 (2.3)



Domain 2: Access to Targeted Case Management

A variety of data sources contributed to the evaluation activities for Domain 2, *“enrollees who access TCM services will access needed medical, social, educational, and other services at a rate higher than others with similar levels of lead exposure”*. Data was reported by GHS obtained through tracking they instituted during the operational period of TCM services. Also, administrative and survey data from enrollees and TCM providers garnered additional information. Four sub-hypotheses were identified for testing. Currently available results reflected the total cohort of TCM participants. Access to a comparison group matched on BLL is in progress.

Sub-hypotheses 2.1-2.2: Improved Access to TCM

- 2.1: *Referral source and participation levels with TCM will be tracked among enrollees.*
- 2.2: *All TCM participants will have an annual assessment conducted.*

Table 25 provides information on the number of beneficiaries that GHS screened for eligibility and enrollment into the Flint Waiver and TCM services. The count of individuals decreased over time as expected with the bulk of referrals occurring at the time of waiver approval. The reported counts also included clients served by GFHC. GHS staff reported that most referrals were received from Medicaid Health Plans. These were not “warm” referrals but rather spreadsheets containing contact information which may have impacted participation. GHS staff further described being contacted by several Community Mental Health organizations in different areas of the state where FME enrollees had relocated; none of these organizations ultimately provided formal TCM services.



Table 25. GHS Reported Flint Medicaid Expansion Waiver Consumer Reporting

Flint Water Waiver Aggregate Numbers				
Category	# of Unique Consumers			
	T2: 5/1/2015— 4/30/2016	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019
Consumers Referred to GHS for FME	0	1018	281	174
Consumers Screened by GHS for FME	0	1018	281	174
Screening Outcome		N (%)	N (%)	N (%)
Consumers Newly Enrolled in FME	0	249 (24.4)	106 (37.7)	123 (70.7)
Consumers Declining Enrollment in FME	0	10 (1.0)	4 (1.4)	1 (0.6)
Already Enrolled/Unable to Contact*	0	759	171	50
Consumers Having Annual Assessment	0	158	91	61

*Separate counts currently not available

As expected, the majority of GHS’ TCM activity occurred during the first year the waiver was available. Referrals to GHS declined over time which aligns with overall enrollment patterns. This finding suggests possibly two scenarios: 1) most people who were eligible and in need of TCM services were screened at the initial offering of the waiver; 2) the screening and enrollment process at GHS has become more refined. Because of the interest in expediting TCM service delivery, some data elements that would have been informative for later evaluation were not identified for capture through specific fields. These elements are often present in progress notes and as the EMR data continues to be evaluated, data abstraction for these elements may occur. ***The EMR data was determined as unsuitable for abstraction and reconciliation with administrative and survey data. The system is intended for case management purposes rather than reflecting a complete health record. After consultation with GHS and their system vendor, the ability to pull information just related to TCM services is not apparent. These data are intermingled with other sensitive data not necessarily related to the water crisis.***

Low participation with TCM was also documented using administrative data sources per Table 26. Specific codes were authorized for billing of TCM annual assessments (CPT T2024) and follow-up visits (CPT T1027). Although a formal comparison group was not available for the hypothesis testing as of the time of this interim report, TCM service utilization was examined in

the FME enrolled population statewide. Analyses confirmed these procedure codes were not highly utilized by these beneficiaries. Variation was observed between the manual tracking put in place at GHS compared to the counts reported through claims data. Investigation into these discrepancies has not yet occurred although the relative scale of participation is consistent.

Table 26: Number and Proportion of Total FME Enrollees Using TCM Services per Administrative Health Care Data

Category	# of Unique Enrollees		
	T3: 5/1/2016— 4/30/2017	T3: 5/1/2017— 4/30/2018	T3: 5/1/2018— 4/30/2019
Statewide FME Enrollees with either T2024 or T1027 TCM billing code	1519 (3.1)	1693 (3.5)	2032 (4.3)
Statewide FME Enrollees with T2024 (assessment)	142 (0.3)	37 (0.1)	52 (0.1)
Statewide FME Enrollees with a Reassessment T2024 TCM billing code	1087 (2.2)	1272 (2.6)	1478 (3.1)

Provider reported (GHS, MDHHS) metrics of TCM participation were found to be less than that reported through the Wave 1 beneficiary survey. Approximately 10% of survey respondents overall reported accessing these services. This may reflect an enhanced sensitivity of survey participants to the water crisis. Those interested in taking advantage of the TCM services may be more likely to take the opportunity to respond to the survey as they were more invested in the program.

Table 27: Utilization of Targeted Case Management (TCM) Reported per Beneficiary Survey

Question	Child N=2321	Adult N=221	Total N=2542
Have you ever used any Family Supports Coordination/Targeted Case Management services (for your child) since enrolling in the Flint Medicaid waiver?	N (%)	N (%)	N (%)
Yes	238 (10.3)	26 (11.8)	264 (10.4)
No	2083 (89.7)	195 (88.2)	2278 (89.6)

The evaluation team also conducted Key Informant Interviews with TCM Professionals at GHS and GFHC to obtain additional qualitative information regarding the services and client receptivity. Representatives of both organizations indicated they were able to accommodate all clients and referrals that had been received to date. Currently available staffing levels did not require stratification or triage of referrals.



Data to identify potential reasons for the low uptake of TCM services were not explicitly identified. According to the beneficiary survey, most (>80%) that participated with the program expressed some level (extremely or somewhat) of satisfaction with their experience. The full summary of the Wave 1 survey is available in Appendix 4. TCM Professionals identified some operational aspects that had opportunities for improvement. For example, TCM providers noted that enrollees sometimes became frustrated with the time it took to put treatment plans into action. They stated that this often was attributed to factors outside of their organizations that hindered receipt of services. It is possible that individual enrollees experiencing delays communicated this to others covered through the waiver adversely affecting interest in participation.

Sub-hypotheses 2.3-2.4: Improved Access to TCM

Two additional sub-hypotheses were developed to document the impact of TCM on individual receipt of care. The logic was enrollees who participated with the TCM program received additional encouragement and assistance in recognizing the importance of the identified screenings and mitigating barriers to securing these screenings. While the waiver itself was hypothesized to increase access to care, TCM specifically was hypothesized to maximize the impact through direct assistance to enrollees in navigating the health care system.

- 2.3: *A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants.*
- 2.4: *A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants.*

During the analytic processes, the evaluation team recognized the use of applicable procedure codes in Medicaid beneficiaries who did not appear to be enrolled in the waiver specifically. When evaluating the interim patterns associated with overall receipt of well-child exams, available data suggested that individuals receiving TCM services were more likely to have more visits compared to waiver enrollees overall. Due to ongoing cleaning and validation, data for these hypotheses are suppressed for this interim report. ***This process has been concluded during 2020 and results will be presented in the 2020 Evaluation Annual Report.***



Domain 3: Improved Health Outcomes

A variety of data sources contributed to the evaluation activities for Domain 3, “*Enrollees will have improved health outcomes compared to others with similar levels of lead exposure*”. Not all administrative measures were available for this interim report. Six sub-hypotheses were identified. Three of these were deemed provisional at the time of approval since it was unclear whether the evaluation team would be granted access to the necessary data. As of this report date, confirmation has been received that individual level data maintained by the MDE and protected under FERPA laws would not be provided for evaluation purposes. In response, the evaluation team drafted education related questions to include into beneficiary surveys.

Sub-hypotheses 3.1-3.2: Improved Health Outcomes

- 3.1: *Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures.*
- 3.2: *Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures.*
- Provisional 3.4: *Descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.*
- Provisional 3.5: *Descriptive analysis of behavioral health conditions and supportive care among enrolled children.*
- Provisional 3.6: *Descriptive analysis of educational delays among enrolled children.*

As stated earlier a comparison group is in the process of being identified. ***The comparison community has been identified and will be Medicaid enrollees residing in Saginaw County. Administrative data for this cohort from 5/1/2013 – 4/30/2020 have been acquired.*** Given a comparable population in Michigan, improved health outcomes in relation to the waiver expanded services will be examined for sub-hypotheses 3.1 and 3.2. For the purposes of this interim report, available beneficiary reported health outcomes from the Wave 1 survey are provided to address sub-hypotheses 3.3.

Sub-hypotheses 3.3: Improved Health Outcomes

- 3.3: *Enrollees report an increase in their self-reported health status over the duration of their enrollment.*

A health status ranking of *good* was the largest category for both the child and adult respondents. Approximately 80% of participants classified their health in the top three rating categories (Table 28). The child survey participants were more likely to report excellent and very good ratings compared to the adults.



Table 28: Self-Reported Overall Health Status

Question	Child N=2344	Adult N=223	Total N=2567
In general, how would you rate your (child’s) overall health (both physical and behavioral/emotional) since enrolling in the Flint Medicaid Waiver?	N (%)	N (%)	N (%)
Excellent	537 (22.9)	29 (13.0)	566 (22.0)
Very Good	662 (28.2)	53 (23.8)	715 (27.8)
Good	698 (29.8)	84 (37.7)	782 (30.4)
Fair	373 (15.9)	45 (20.2)	418 (16.3)
Poor	74 (3.2)	12 (5.4)	86 (3.4)

Health status ratings were then subdivided by physical and behavioral/emotional health aspects. The experience of the individuals affected by the Flint Water Crisis has been shown to have significant impacts on emotional well-being as published by other sources. The survey estimates reinforce this observation with generally higher rankings for physical health compared to behavioral/emotional health. Tables 29 and 30 show just 2.9% reported having poor physical health compared to 12% rating behavioral/emotional health as poor.

Table 29: Self-Reported Physical Health Status

Question	Child N=2339	Adult N=223	Total N=2562
In general, how would you rate your (child’s) physical health since enrolling in the Flint Medicaid Waiver?	N (%)	N (%)	N (%)
Excellent	610 (26.1)	36 (16.1)	646 (25.2)
Very Good	698 (29.8)	54 (24.2)	752 (29.3)
Good	659 (28.2)	75 (33.6)	734 (28.6)
Fair	315 (13.5)	40 (17.9)	355 (13.8)
Poor	57 (2.4)	18 (8.1)	75 (2.9)



Table 30: Self-Reported Behavioral/Emotional Health Status

Question	Child N=2336	Adult N=222	Total N=2558
In general, how would you rate your (child's) behavioral/emotional health since enrolling in the Flint Medicaid Waiver?	N (%)	N (%)	N (%)
Excellent	412 (17.6)	30 (13.5)	442 (17.3)
Very Good	456 (19.5)	41 (18.5)	297 (19.4)
Good	650 (27.8)	49 (22.1)	699 (27.3)
Fair	542 (23.2)	69 (31.1)	611 (23.9)
Poor	276 (11.8)	33 (14.9)	309 (12.1)

Wave 2 of the enrollee survey was concluded June 2020. Those data are being incorporated at this time and longitudinal data to document any variation from prolonged waiver participation will be presented in the 2020 Evaluation Annual Report.

Comparison datasets containing historical data back to 2013 for Genesee County and Saginaw County have been identified. These sources include County Health Rankings published by the University of Wisconsin and the Behavioral Risk Factor Surveillance Survey containing health status question(s). These sources have online reports at the county level. Additionally, historic reporting back to 2013 is available. The evaluation team is further investigating the Michigan Kids Count reporting available from the Michigan League for Public Policy for the ability to refine to county level.

Sub-hypotheses 3.4-3.6: Improved Health Outcomes

- Provisional 3.4: *Descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.*
- Provisional 3.5: *Descriptive analysis of behavioral health conditions and supportive care among enrolled children.*
- Provisional 3.6: *Descriptive analysis of educational delays among enrolled children.*

Several items of the Beneficiary Child Survey addressed behavioral and developmental issues. The following summary of these items addressed sub-hypotheses 3.5 and 3.6. Most of the parents reported their children were in the expected grade level in Wave 1 (Table 31). Three-quarters of respondents denied being informed their child should be tested for learning disabilities.



Table 31: Child Educational Status Reporting

Question	Yes	No	Not in School	Total
	N (%)	N (%)	N (%)	N
Is your child in the grade level expected for his or her age?	1603 (69.4)	368 (15.9)	340 (14.7)	2311
Has anyone told you that your child should be tested for learning problems?	542 (23.8)	1731(76.2)	--	2273

Respondents to the child survey were also asked to report if they had been informed by either a health care professional or daycare/school professional the child had a behavioral or emotional problem. Approximately 25% did acknowledge being so informed (Table 32).

Table 32: Child Behavioral/Emotional Problem Reporting

Question	Yes	No	Not in School	Total
	N (%)	N (%)	N (%)	N
Have you ever been told by a doctor or nurse that your child has a behavioral or emotional problem?	534 (22.4)	1751 (76.6)	--	2285
Has a daycare or school teacher or school nurse ever told you that your child has a behavioral or emotional problem?	595 (25.9)	1507 (65.7)	191 (8.3)	2293

For future reporting of Hypotheses 3.4-3.6, the evaluation team will access the Mi Schools Dashboard in addition to using the self-reported data from the enrollee surveys to address Domain 3 hypotheses regarding improved health outcomes pertaining to school and cognitive development. Outcomes identified in the Education Data section will be reported for school district level (for the Target of Flint Community Schools and the comparison community of Saginaw Schools), across several age groups including infant, preschool, and across selected grades.

For Hypothesis 3.4, children diagnosed with serious emotional disturbance and other serious educational/behavioral delays will be examined using administrative data and Mi Schools data using the rates of diagnosed Cognitive Impairment and Emotional Impairments. For Hypothesis 3.5, reporting on descriptive analyses of behavioral health conditions of the child enrollees will be taken from the enrollee survey that asks about child behavioral health and available school data. Data will also be obtained from the Flint and Saginaw school districts for suspensions and expulsions for available years. Although these outcomes will not be specific to enrollees, aggregate rates for years before and after the water exposure will be



reported. For Hypothesis 3.6, the Mi Schools Student Counts Report offers rates and statistics for students who have Independent Education Plans (IEP)/Special Education for educational and cognitive delays. Special education variables include: school age cognitive and emotional impairment, Early Childhood Developmental Delay (pre-school) and infant delay (age 0-3 years).

Descriptive information from the Neurodevelopmental Center of Excellence (NCE) about referral sources and needs have been requested however the data may not be made available. Therefore, the Mi Schools Dashboard will serve as the primary data source for these hypotheses and the evaluation team plans to incorporate any information that is forthcoming from the NCE as contextual factors. Unfortunately, the NCE was significantly affected by the COVID-19 pandemic and was closed for most of 2020. Thus, the penetration of their services into the community has been much smaller than the evaluation team originally anticipated.



Domain 4: Lead Hazard Investigation

The evaluation team continue to explore data reporting options for Domain 4, *“The lead hazard investigation program will reduce estimated expected ongoing or re-exposure to lead hazards in the absence of this program.”* Particularly, direct access to information regarding lead hazard mitigation services are housed outside of MSA. The intent was for expansion of lead screening and investigation services for individuals affected by the water but not having a documented elevated BLL. The assumption was that early identification of environmental exposures or risks could ensure access to services intended to minimize those risks. Two sub-hypotheses were identified however the evaluation team continues to explore methods to report. As with the data limitations encountered for education data, the evaluation team drafted lead exposure related questions to include into beneficiary surveys to provide some information. The TCM Providers further identified the lack of safe water as an ongoing exposure risk.

Sub-hypotheses 4.1-4.2: Lead Hazard Investigation

- 4.1: *Enrollees without elevated blood lead levels and participating with TCM services will access lead hazard investigation services to the same degree as beneficiaries with elevated blood lead levels.*
- 4.2: *Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation.*

According to the beneficiary survey participants, slightly more than half continue to use water supplied by the Flint water system.

Table 33: Use of Flint Water Supply

Question	Child N=2332	Adult N=224	Total N=2556
Do you (your child) use water supplied by the City of Flint, also known as tap or faucet water right now?	N (%)	N (%)	N (%)
Yes	1186 (50.9)	142 (63.4)	1328 (52.0)
No	1146 (49.1)	82 (36.6)	1228 (48.0)

Among those who use the water, almost two-thirds have continued using the water for activities where ingestion is likely (i.e. drinking/cooking/brushing teeth or washing dishes).



Table 34: Activities Using Flint Water Supply

Question	Child N=1186	Adult N=142	Total N=1328
What do you use tap water for? Check all that apply.	N (%)	N (%)	N (%)
Drinking/cooking/brushing teeth/washing dishes	800 (67.4)	99 (69.7)	899 (67.7)
Bathing/showering/washing clothes	1132 (95.4)	125 (88.0)	1257 (94.6)
Watering garden/pools/sprinklers	403 (34.0)	42 (29.6)	445 (33.5)
Other	82 (6.9)	13 (9.2)	95 (7.2)

Full remediation of water as an exposure threat will only be completed when the water service lines have been fully replaced. Although this is a community priority, work is expected to continue through 2020 before this is finished.

Although the evaluation team has not yet tested these hypotheses for this enrolled population, the collaboration with the CDC funded Flint Registry has provided community level information regarding lead exposures. The 2017 Flint Lead Free Report provided a comprehensive summary of trends emphasizing the lead prevention efforts. A copy of the report is available in Appendix 6. Notably, the percent of residential water testing with elevated lead levels has decreased from 2015 to 2017 and the number of environmental investigations has increased from 2015 to 2017. With respect to the waiver’s authorization of expanding Lead Safe Home Program services to the targeted population without documented elevated BLL, the proportion of investigations for children not having the extreme levels increased from approximately 13% in 2015 to 76% in 2017.

The blood lead levels available in the Michigan Lead Poisoning and Prevention data sets have been obtained which will further the testing of these hypotheses. The team continues the collaboration with the Flint Registry to obtain updated Flint Lead Free reports to provide community data regarding ongoing water testing and environmental investigations.



Conclusions

This Flint Water Crisis affected a distinct community that was already, and continues to be, an economically vulnerable and exposed to environmental and social stressors.^{1-2,6} The FME waiver was established in part to address resulting health effects and improve health outcomes for the next generation. Based on the available evaluation data from 2018 through 2019, the demonstration appears to have been successful in achieving the goals and objectives, albeit to different standards. Several measures in the Access to Care domain demonstrated rate increases while others remained stable. The Access to TCM and Improved Health Outcomes domains were further supported by beneficiary feedback. Analyses on the last domain Lead Hazard Investigation remain pending at the time of this interim report. Collaboration with Flint Registry colleagues provide data to suggest this is improving in the community at large from 2015 through 2017.

Despite being in operation for over three years, enrollment continues to be less than originally estimated. Original **MDHHS** estimates identified 15,000 additional individuals who would have been eligible for the coverage due to the expanded eligibility in addition to the 30,000 that were already covered by Medicaid. The total enrolled population reached approximately 34,000 and has been decreasing over time which confirms MDHHS enrollment tracking. In this interim report, it is not possible to ascertain concrete factors that may have resulted in under-enrollment. Some of the under-enrollment may be attributed to resources that entered the Flint and Genesee County community before formal federal resources were implemented such as FME. There remain opportunities for eligible individuals to enroll in the waiver. The Flint Registry is fully operational and serves as a hub for managing referrals.

Despite encountering lower participation than originally envisioned, enrolled beneficiaries are benefiting as evidenced by administrative data, survey responses, and TCM key informant interviews. The evaluation team has documented increased utilization of services such as lead screening for children and pregnant woman. This supports good clinical practice even in non-crisis situations. Enrollees report satisfaction with the benefits. The benefits to enrollees appear to extend beyond addressing only the potential lead impacts. Those with chronic conditions report increased confidence and resources available to them for self-management.

Preliminary results also suggest an increase in developmental and behavioral screening. Not only is this a preventative measure in communities faced with environmental lead exposure but an opportunity for increased awareness for health providers and parents in socioeconomic compromised communities. Early treatment of developmental and behavioral issues is the key to mitigating long-term consequences. Parents of affected children, whose health outcomes from lead exposure may not appear until school age and puberty, are expected to have increased need of and uptake in services in the future and begin to utilize expanded services. In



addition, the NCE began taking referrals in late 2018 and may potentially increase enrollment in FME.

The TCM benefit was used to a lesser degree than anticipated. The highest estimate of uptake came from the beneficiary survey indicating just 10% of enrollees using this. However, although the population penetration of this service was low, those that participated reported being satisfied. In addition, both beneficiaries and case managers reported that rapport is increasing, and most beneficiaries meet with case managers in their homes. This may indicate an element of trust that was not readily anticipated.

One unexpected change to survey design resulted in significant efficiency to the survey process. In response to community input, a web-based version of the beneficiary survey was implemented in addition to the planned phone and mail surveys. Several protections were put into place to ensure participants could only complete one survey and that non-waiver enrollees couldn't find the survey through internet search engines. Nearly half of all survey responses came in through the web option. This provided timelier data as well as reduced the amount of "bad data" that resulted from inattention to skip patterns that can occur on paper surveys. The web-based survey offered respondents the option to provide an email address for subsequent waves. The success of this method of Wave 2 reminders will be forthcoming in a future report.

Despite the impacts of the coronavirus pandemic and associated government shut-downs, the evaluation work continued during 2020. An additional year of T3 data covering 5/1/2019 through 4/30/2020 was pulled and is being incorporated. Due to the receptivity of the enrolled population to participate with online survey methodology, Wave 2 was able to be continued during the year and Wave 3 was implemented. Wave 2 data collection concluded in June 2020 and the results will be incorporated into the upcoming 2020 Evaluation Annual Report. Although some data sources originally specified to support the evaluation activity have been determined to be unavailable, local and state reference community reports containing similar proxy measures have been identified and are being incorporated.

The current timing of the required reporting with the waiver approval and enrollment dates makes it difficult to include the most recent 12-month experience of health care administrative data because of the need to allow sufficient time for claims processing. MDHHS partners have estimated fee-for-service professional claims are 92% complete at three months and 94% at four months. Managed care encounter data lag an additional 30 days. Thus, in order to be reasonably confident in having at least 90% of total health services documented in the Medicaid administrative data, a minimum four-month period is needed.

We propose to continue the waiver evaluation period so that the full 12-month reporting cycle of administrative data could be obtained August 2021. This would result in the final evaluation report being submitted October 31, 2021.



Interpretations, Policy Implications and Interactions with Other State Initiatives

Clear and intentional coordination of Medicaid coverage with other programs and efforts to provide a full suite of services e.g. prenatal services, behavioral health services, child development services and timely, preventative screening is needed for those affected by the Water Crisis. Not only at the time of the event, but ongoing in order to sustain healthy behaviors, in general.

An example of collaboration with other initiatives occurred with the environmental lead assessment activities. As of January 1, 2017, CMS and the State of Michigan worked together on a Michigan State Plan Amendment. The collaboration resulted in a five-year Title XXI state designed Health Services Initiative (HSI) to cover expanded lead abatement services in the impacted areas of Flint for children and pregnant women. Although not directly a medical benefit, this partnership supports the health and well-being of individuals.

TCM key informants did indicate that ongoing training and education for expanded services of the FME waiver eligibility, particularly for referral making health personnel is still needed. It was also noted the referral process is often complicated. Other considerations include offering comprehensive guidance to providers and community partners about eligibility for coverage, especially in the higher income levels persons. Likewise, enrolled beneficiaries may need education about specialized services (TCM) and what these services include to address health effects possibly related to the water crisis.



Lessons Learned and Recommendations

This interim report details the first two years of the evaluation and offers information that can improve not only the present evaluation, but future Medicaid Expansion evaluations for similar environmentally related health emergencies. In this report, we found that the uptake in enrollment remains lower than expected. Reasons for this are not fully discernable at this time, but subsequent reports may reveal information that can explain this phenomenon. For instance, communication to the public, provider community, and potential beneficiaries may require ongoing multi-media dissemination. Thus, it is recommended that there be early and clear communication to the community and health providers about access methods and conditions of the expanded waiver eligibility along with ongoing training.

The newly approved service of TCM has been utilized much less than anticipated despite the reports of satisfaction from those who do engage. There may be several reasons for this observation including that those who have participated and experienced delays in being able to secure the referrals may be sharing those experiences with others. This could result in those who may have considered participating being discouraged from doing so. Another possible reason for lack of engagement was a degree of altruism. According to the TCM providers, some individuals who were resistant to participation expressed concern they would be taking services away from someone who had a more acute need. In addition, ancillary services that aided residents during the height of the crisis and beyond may have resolved some issues that would be serviced by the expansion.

The beneficiary survey conducted as part of this evaluation presented a unique opportunity to test various methods of survey participation. Conventional wisdom and previous research suggest that vulnerable populations who utilize Medicaid services do not use web-based services because of lack of knowledge or access to the internet.⁷ The beneficiaries enrolled in the waiver suggested an online survey option to the evaluators. This was accommodated and, in turn, participation with the web-based survey exceeded the telephone or paper versions of the survey. Not only was this method preferred by individuals, the online options provided benefits not realized through paper or telephone. Specifically, the turn-around time to receive the data was reduced, the cost was less per survey since fewer survey staff were required and the issue of “bad data” from inattention to skip patterning was eliminated. It is important to acknowledge a small incentive was provided to all participants upon completion of the survey, regardless of modality. The team cannot be sure whether the incentive or the mode was a primary driver in a decision to participate.

The willingness of online interaction may represent opportunity for expanded outreach to a Medicaid population. Web-based access to health service information and referrals may reduce



barriers to accessing healthcare services. The use of web-based services can offer substantial cost savings for delivery of healthcare for federal and local health systems.

A full description of recommendations is limited at this time. The period of this interim report covers evaluation activities from 2018 through 2019. The evaluation is expected to continue through April 2021. As additional data sources are incorporated, utilization estimates and beneficiary ratings may change from the provisional data reported here. However, currently available data suggest that the waiver has been successful in meeting most goals and objectives.



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Appendix 1: Matrix of Evaluation Domains including Hypotheses and Measures

Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
DOMAIN 1: Access to Care			
H1.1: A greater proportion of enrollees will obtain age-appropriate well-child exams compared to others with similar lead exposures.	1. Well Child Visits in the First 15 months of Life	National Committee for Quality Assurance/NQF 1392	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	2. Well Child visits in the Third, Fourth, Fifth and Sixth Years of Life	National Committee for Quality Assurance/NQF 1516	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	3. Adolescent Well-Care Visits	National Committee for Quality Assurance	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
H1.2: A greater proportion of enrollees will receive age-appropriate developmental screening/assessments compared to others with similar lead exposures	1. Developmental Screening in the First Three Years of Life	Oregon Health & Science University /NQR 1448	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	2. Socio-emotional/ Behavioral Screening for Children 4-17 years of age	n/a	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
H1.3: A greater proportion of enrollees will receive age appropriate lead testing compared to others with similar lead exposures	1. Lead Screening in Children	National Committee for Quality Assurance	Administrative claims/encounters in the MDHHS Health Services Data Warehouse



Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H1.4: A greater proportion of enrollees with high blood lead levels will receive re-testing at the appropriate intervals compared to others with similar lead exposures	1. Follow-up of elevated blood lead level	Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)- CMS/American Academy of Pediatrics	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to lead screening and TCM monitoring data
H1.5: Enrollees who are pregnant will have more timely prenatal and postpartum care compared to others with similar lead exposures.	1. Timeliness of Prenatal Care	National Committee for Quality Assurance/NQF 1517	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records
	2. Postpartum Care	National Committee for Quality Assurance/NQF 1517	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records
H1.6: A greater proportion of enrollees who are pregnant will have recommended lead testing compared to others with similar lead exposures	1. Lead screening in pregnancy	American Congress of Obstetricians and Gynecologists	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records data
H1.7: A greater proportion of enrollees will participate with home visiting services compared	1. Maternal Infant Health Program Participation	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to MIHP visit and TCM monitoring data



Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
to others with similar lead levels.			
H1.8: Enrollees will attest to improved access to health care as a result of the expanded coverage.	1. Enrollee Attestation for Improved Access to Care	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	Beneficiary survey responses
H1.9: Enrollees will report satisfaction with their ability to access health care as a result of the expanded coverage.	1. Enrollee satisfaction with Medicaid expansion coverage	Agency for Healthcare Research and Quality – Consumer Assessment of Healthcare Providers and Systems (AHRQ-CAHPS) Question Modification	Beneficiary survey responses
DOMAIN 2: Access to Targeted Case Management			
H2.1: Referral source and participation levels with TCM will be tracked among enrollees	1. Referral Source for TCM	MI defined measure	TCM documentation visit data
	2. TCM Participation	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to TCM billing/documentation
H2.2: All TCM participants will have an annual assessment conducted.	1. Annual TCM assessment	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to TCM billing/documentation



Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H2.3: A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants	1. A greater proportion of TCM participants will have age-appropriate well child exams compared to TCM non-participants	National Committee for Quality Assurance /NQF 1392	TCM Program documentation linked to Administrative claims/encounter data available through the MDHHS Health Services Data Warehouse
H2.4: A greater proportion of TCM participants will have completed age-appropriate developmental screening compared to TCM non-participants	1. Impact of TCM in assuring enrollees obtain age-appropriate developmental screenings.	Oregon Health & Science University/NQF 1448 and new evaluation measure (socio-emotional/behavioral screening)	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to TCM billing/documentation visit data
DOMAIN 3: Improved Health Outcomes			
H3.1: Enrollees will have higher completed age-appropriate immunization statuses compared to others with similar lead exposures	1. Childhood Immunization Status	National Committee for Quality Assurance/NQF 0038	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
	2. Immunizations for Adolescents	National Committee for Quality Assurance/NQF 1407	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
H3.2: Enrollees who are pregnant will deliver infants with higher birth weights compared to others with similar lead exposures	1. Low Birth Weight Rate	Agency for Healthcare Research & Quality/NQF 0278	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Vital Records



Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
H3.3: Enrollees report an increase in their self-reported health status over the duration of their enrollment.	1. Enrollee Self-Reported Health Status	AHRQ/CAHPS Question Modification	Beneficiary survey responses
	2. Enrollee Self-Reported Efficacy of Chronic Condition Management	Adult and Pediatric Condition Management Self-Efficacy (ex. Asthma Control Test)	Beneficiary survey responses
<i>PROVISIONAL</i> H3.4: Descriptive analysis of the proportion of children diagnosed with severe emotional disturbance and other developmental/learning disabilities including comparing rates to others with similar lead exposures.	1. Proportion of enrollees having diagnosis code(s) of interest	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse
<i>PROVISIONAL</i> H3.5: Descriptive analysis of behavioral health conditions and supportive care among enrolled children.	1. Prevalence of behavioral health conditions among enrolled children 2. Count of children enrolled in Early Childhood Programs 3. Proportion of students in Kindergarten who	MI defined measure	Beneficiary survey responses MDE Data Summary data available through MI Schools Dashboards



Hypotheses	Measures	Steward/NQF #	Targeted Data Source(s)
	participated in Early Childhood Programs		
<i>PROVISIONAL</i> H3.6: Descriptive analysis of educational delays among enrolled children.	<ol style="list-style-type: none"> 1. Prevalence of educational delays among enrolled children 2. Counts of children remaining in same grade 3. Educational Progress Standardized Testing (M-STEP, MI-Access) 	MI defined measure	Beneficiary survey responses MI-Data Summary data available through MI Schools Dashboards
<i>DOMAIN 4: Lead Hazard Investigation</i>			
H4.1: Enrollees without elevated blood lead levels and participating with TCM services will access lead hazard investigation services to the same degree as beneficiaries with elevated blood lead levels.	<ol style="list-style-type: none"> 1. Prevalence of Lead Hazard Assessment/Investigation 	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Blood lead levels
H4.2: Beneficiaries found to be at risk for ongoing lead exposure will be referred for additional environmental investigation	<ol style="list-style-type: none"> 2. Prevalence of Lead Hazard Follow-up Investigation 	MI defined measure	Administrative claims/encounters in the MDHHS Health Services Data Warehouse linked to Blood lead levels



Appendix 2: Approved Evaluation Plan



Flint Expansion
Evaluation Final2_CM



Appendix 3: Beneficiary Survey Summary Report and Materials



FME_Wave
1SurveyReport_1_6_21



prenotif_Flint_benie_
child.pdf



cover
letter_Flint_benie_chil



Child_formatted_final
.pdf



prenotif_Flint_benie_
adult.pdf



cover
letter_Flint_benie_adu



Adult_formatted_fina
l.pdf



Reminder_SurveyMai
l1.pdf



Nonresponder_Surve
yReminderLetter_Mail



Appendix 4: TCM Provider Key Informant Summary Report and Materials



TCM_Provider_summary_1_6_2020.pdf



TCM_ProviderSurvey_phone.pdf



Appendix 5: MSU Human Research Protection Program – Determination Letter



MSU HRPP
Determination Letter.



Appendix 6: Flint Lead Free 2017 Report, Flint Registry



Lead-Free-Report-V5.
pdf



Appendix 7: Comparison Group Selection



Appendix 7
Comparison group s