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# Assessment of the study on Enhanced Disease Surveillance and Environmental Monitoring in Flint, Michigan

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Final

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# Summary

In 2014 and 2015 two outbreaks of Legionnaires' Disease were observed in the City of Flint. The outbreaks coincided with a change in drinking water quality in April 2014, when the city's source for drinking water production and treatment was switched. To better protect the people of Flint, the Flint Area Community Health and Environment Partnership (FACHEP) was established to execute a large, complex, and multidisciplinary project entitled "ENHANCED DISEASE SURVEILLANCE AND ENVIRONMENTAL MONITORING IN FLINT, MICHIGAN."

Because of a growing dispute between the client (State of Michigan, MDHHS) and the FACHEP team, the State of Michigan asked KWR to serve as an external, independent project oversight party, to oversee the project being conducted by FACHEP. KWR carried out a scoping mission to better understand all issues concerned in order to determine whether KWR has the knowledge, skills, and disposition to act as project oversight team on behalf of the client (MDHHS).

In the limited time of the scoping mission, KWR was not able to do an in-depth analysis of the FACHEP project and the oversight process. The KWR scoping team only had a 1.5-hour meeting with the Principal Investigator of FACHEP because the appointment had to be made on short notice. Therefore a balanced hearing of all sides did not take place. Nevertheless, KWR feels that on the basis of its scoping mission the following conclusions can be drawn:

1. Basic conditions for project oversight are lacking. This makes proper project oversight almost impossible for the client or for any party that would represent the client.
2. The current status of the project and circumstances surrounding the project do not help promote basic project oversight.
3. Consensus among FACHEP and MDHHS on the outcome of the research, as well as on its implications for public health, is currently lacking.
4. The scientific output of the project that KWR has seen is very limited thus far, both with regard to quality and quantity. The quantity of the work does not seem to match the time and budget spent, nor does it appear to match the ambitions raised at the beginning of the project. However, more outcome is expected, so that final conclusions on this point cannot be drawn yet.

Despite all the good intentions underlying the establishment of FACHEP, the major problem is that there is no trust between the client and the contractor, and that the circumstances around the project (legal issues, constant attention from public and media) stand in the way of developing a climate where sound, unbiased and responsible research is promoted. The result is a project where the roles of research, communications, project management, and project oversight are completely unclear, and where there are different views, both based on scientific data, with regard to the relationship between the outbreaks of Legionnaires' Disease and the change in the Flint water source.

KWR would recommend that the possibilities of overcoming the trust problem be further explored, and that an agreement be reached to establish an independent review of both the scientific research and the public health communications.

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Besides the independent review, KWR would be prepared and willing to do the project oversight on behalf of MDHHS, under the condition that the above mentioned issues will be addressed in a prolongation of the research. This prolongation comprises the renegotiation of the contract in which project management principles are put in place, roles are completely clear, and independent review of scientific research and public health communications is guaranteed.

KWR greatly appreciates the assistance it received in conducting its mission from the Governor's Office, the Michigan Department of Health and Human Services, and the Principal Investigator of FACHEP and members of his staff at Wayne State University.

# Contents



Final

# 1 Introduction

## 1.1 Background scoping mission

In 2014 and 2015 two outbreaks of Legionnaires' Disease were observed in the city of Flint. The outbreaks coincided with a change in drinking water quality in April 2014, when the city's source for drinking water production and treatment was switched. To better protect the people of Flint, the Flint Area Community Health and Environment Partnership (FACHEP) was established to execute a large, complex, and multidisciplinary project entitled "ENHANCED DISEASE SURVEILLANCE AND ENVIRONMENTAL MONITORING IN FLINT, MICHIGAN.". The project was commissioned through the governor's office and the contract with FACHEP was initiated and financed by the Michigan Department of Health and Human Services (MDHHS). FACHEP is led by a team of researchers of Wayne State University, and is executed in collaboration with other universities/institutes. Phase I was the scoping phase of the project and was finalised in 2016. The current project is called "Phase II". The objectives of Phase II of the project are:

1. To reduce the occurrence of legionellosis, hospitalizations and deaths due to legionellosis to levels at or below those seen in years prior to 2014.
2. To define potential sources of *Legionella* exposure in residential households and high-risk facilities.
3. To develop evidence-based approaches for reducing exposure to *Legionella* among Flint residents.
4. To strengthen existing capacity in infrastructure, institutions and groups of individuals that enhances community resilience in addressing common threats to the health and welfare of community residents.

This project is also collecting information to verify/falsify the hypothesis that the increased incidence of Legionnaires' disease in 2014 and 2015 was caused by the change in the water source. The project runs for about 1.5 years now. The project has resulted in a discussion between the MDHHS and several of the FACHEP research partners on the chosen research approach, methodologies and communication. This dispute between these researchers and MDHHS has deepened and the stress on this relation is increased by the accusation of MDHHS officials with, amongst others, obstruction of justice by the Attorney General's office with respect to this project. This escalation of the dispute makes it difficult for the MDHHS to execute the oversight of (parts of) FACHEP and may affect the achievement of the overall goal of the project, ensure safe drinking water for the people of Flint with regard to Legionella.

The State of Michigan has asked KWR to serve as an external, independent project oversight party, to oversee the project being conducted by the Flint Area Community Health and Environment Partnership (FACHEP). KWR was asked to serve in three roles as independent monitor:

1) Take on project oversight through the final phase of the project period, i.e. until December 2017
2) Make an assessment of the science/methods used
3) Ensure conclusions of the project are based on sound research, acknowledging strengths and limitations of the methods used.

This report describes the results of the scoping mission that KWR carried out to better understand all issues concerned in order to determine whether KWR has the knowledge, skills and disposition to act as project oversight team on behalf of the client (MDHHS).

The goal of the scoping mission was to get a clear idea of the situation and to determine the role KWR can play in project oversight. It was agreed to deliver a document in which the overall structure and management of the project 'ENHANCED DISEASE SURVEILLANCE AND ENVIRONMENTAL MONITORING IN FLINT, MICHIGAN' is assessed, the applied research approaches and methodologies within the project are identified, the preliminary results have been gathered, and the dispute topics between MDHHS and some researchers of the FACHEP consortium are described, and conclusions about the role KWR can play are presented.

### 1.2 Activities scoping mission

The following activities have been undertaken during the project:

1. Understand and evaluate the FACHEP project planning.

   Review contracts, project descriptions, meeting reports and other information and exchanges between MDHHS and the research institutes to understand and evaluate the objectives, intended deliverables, finances and governance of the project.

2. Understand and evaluate the progress of the FACHEP project.

   Review intermediate reports, presentations, meeting reports and interviews with MDHHS and research institutes to understand the current state of the research in FACHEP and the planning of the deliverables.

3. Understand and evaluate the FACHEP research design and methodology.

   Review the information on the study design and methods used in the different research elements of FACHEP (environmental microbiology, epidemiology, community engagement and communication).

4. Understand and evaluate the FACHEP intermediate results.

   Review the results of the different research elements obtained thus far

5. Make an overview of the available intermediate results.

6. Evaluate the constraints of the dispute between MDHHS and research institutes and legal situation.

7. Reporting

The results of the scoping mission have been presented to the client at the end of the scoping mission. The elaborated results of the scoping mission are laid down in this report.

### 1.3 Organization scoping mission: timing and staffing

The activities in the scoping mission were undertaken in three phases: A, B and C:

A. Preparation of the scoping mission in the Netherlands. Preparatory activities were conducted September 1st until October 6th, 2017.
B. Scoping mission: review of methodology with a team of experts on environmental microbiology, academic research evaluation and governance in Lansing, Michigan and a back office in the Netherlands. The scoping mission took take place 9-12 October 2017 and lasted 4 days. The team of the scoping mission comprised 4 experts:
    - Dr. Anthony Verschoor
    - Dr. Gert Doekes
    - Prof. dr. Gertjan Medema
    - Loet Rosenthal MSc

    The back office team comprised 6 experts:
    - Dr. Paul van der Wielen
    - Prof. dr. Bert Brunekreef
    - Prof. dr. Annemarie van Wezel
    - Dr. Laurens Hessels
    - Idsart Dijkstra MSc MBA
    - Nellie Slaats MSc

    Short descriptions of the expertise of the persons involved can be found in Appendix I.
C. Reporting phase. The report was prepared in the weeks after the scoping mission.

# 2 Situational analysis

## 2.1 Project structure and management

The Flint Area Community Health and Environment Partnership (FACHEP) is a team led by researchers from Wayne State University (specializing in environmental engineering and public health) commissioned to perform an independent study with the objectives stated in chapter 1. The hypothesis of FACHEP is that there is an association between changes in changes in Flint drinking water quality in 2014 and 2015 and the prevalence of Legionnaires' disease outbreak in the same period.

The FACHEP project involves researchers from different research organizations within and outside Michigan, and various local health authorities (Figure 1). Major activities include studies on epidemiology, environment (water quality and microbiology) and outreach activities (public health communication).

FIGURE 1. MEMBERS OF THE FACHEP CONSORTIUM

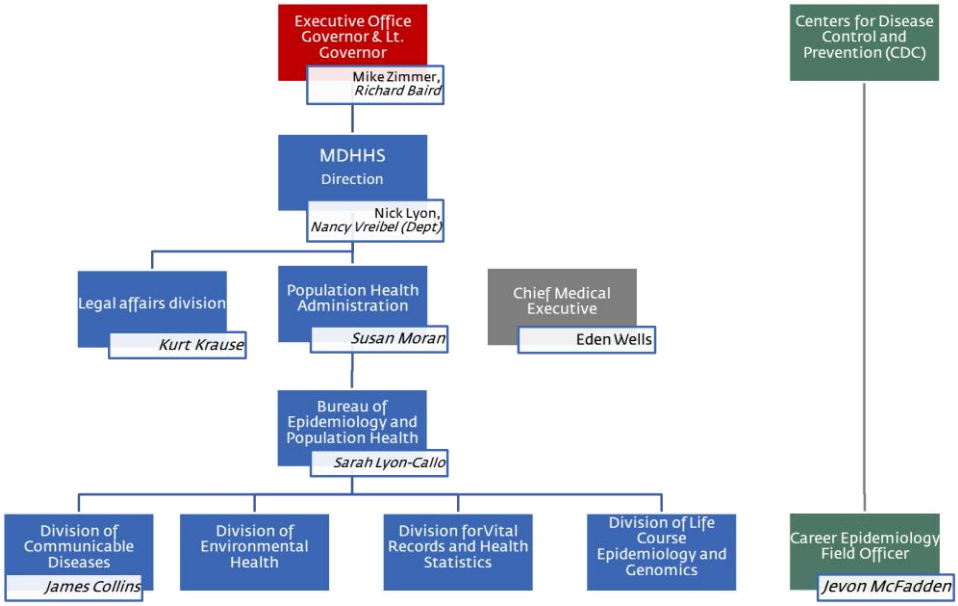
| | |
|---|---|
| Wayne State University (WSU) | • Dept. Civil & Environmental Engineering: **Shawn McElmurry (PI)**<br>• Dept. Communication: Matthew Seeger (Co-PI)<br>• Dept. of Pharmacy Practice: Paul Kilgore (Co-PI)<br>• School of Social Work: Joanne Smith-Darden, Joanne Sobeck |
| University of Michigan (UM) | • Dept. of Microbiology and immunology: Michele Swanson<br>• Dept. of Civil & Environmental Engineering: Nancy Love |
| Kettering University (KU) | • Liberal Studies: Benjamin Pauli<br>• Mechanical Engineering, Laura Sullivan (Co-PI) |
| Michigan State University (MSU) | • Dept. Civil and Environmental Engineering: Susan Masten |
| Colorado State University (CSU) | • Dept. of Economics: Sammy Zahran |
| Henry Ford Health System (HFHS) | • Division Infectious Diseases: Marcus Zervos (Co-PI) |
| City of Flint Public Health Authority | • Chief Public Health Advisor: Pamela Pugh |
| Genesee County Health Department (GCHD) | • Health Officer: Mark Valacak (currently retired) |

During the scoping mission, the KWR team has spoken to Dr. Shawn McElmurry, principal investigator (PI) of the FACHEP project (see also Fig. 1), and members of his staff.

## 2.2 Points of concern regarding project oversight

On days 1 and 2, KWR has been working on an initial analysis of the situation, in order to develop a clearer picture of the issues that have upset the current working relationship between MDHHS and FACHEP. The KWR mission team has had meetings with several people from MDHHS, see fig. 2 for an overview.

FIGURE 2. ORGANIGRAM (REPORTING RESPONSIBILITIES) OF MDHHS. NAMES IN ITALICS INDICATE PEOPLE THAT KWR ACTUALLY HAS HAD MEETINGS WITH.




Following these meetings, KWR identified seven points of concern with respect to current project oversight, which are listed below:

1. MDHHS experiences difficulty in overseeing FACHEP and in playing their role as contracting client. This is due to the special setting that MDHHS is experiencing in various ways. Ongoing legal procedures, such as a previously issued Protective Order, are holding back MDHHS. The perception of MDHHS is that project oversight activities such as project review are being considered by FACHEP as trying to (negatively) influence the project results. Furthermore FACHEP was not commissioned and organised as regular MDHHS-projects were. FACHEP feels that they can go up to the governor's office whenever they are met with resistance from MDHHS. FACHEP was commissioned by the governor's office, which has asked MDHHS to initiate the contract with FACHEP, whereas MDHHS usually does not fund research projects. This lack of client experience could also explain that there is a very limited amount of measurable project data (progress reports, performance indicators) to demonstrate that the project is on track with regard to budget spent, organisation, quality assurance, information and schedule. This, combined with the issues mentioned under 4, creates a great sense of unease at MDHHS when trying to oversee the project.
2. MDHHS is concerned about the use of data from MDSS (Michigan Disease Surveillance System, a communicable disease reporting system), particularly for retrospective analyses in the epidemiological investigations being performed. The main points of concern of MHDSS are in the rigor in the design of the epidemiological-studies and in the quality of the surveillance dataset. MDHHS has examples that data quality evaluation is done inadequately by FACHEP, which has led to errors in the research results, such as:
    a. By disregarding cases with missing onset data in the pre-crisis years, pre-crisis Legionellosis incidence rates might have been underestimated systematically;

   b. Insufficient/poor definition of control groups/populations and data needs for specific research questions in the project design;
   c. Insufficient recognition of the origin of the Legionella isolates (McLaren hospital is a regional lab and isolates from McLaren are not necessarily from Genesee county)
3. With respect to point 2, MDHHS has experience that FACHEP is not responsive to concerns that MDHHS expressed to FACHEP about data quality, to the extent that results are communicated externally without prior review by MDHHS
4. MDHHS considers FACHEP to be unresponsive to invitations on scientific discussions about data and methods, with the United States Environmental Protection Agency (US EPA), the Centers for Disease Control and Prevention (CDC), the Michigan State Department of Environmental Quality (DEQ), other local authorities and other possible partners. For instance, they refused to take part in a session in June 2017 organised to discuss the Legionella isolates, stating that they were in conflict with Virginia Tech University (Prof. Mark Edwards). A separate session had to be organised which to date has not taken place. It is not clear how the FACHEP-project is organising the review of their research results. There is a formal 30 day review window available for MDHHS to review FACHEP publications and communications. The FACHEP-researchers working on the environmental part of FACHEP research are usually taking this window into account before publishing their results. The researchers on the epidemiologic component of FACHEP-research have in at least one instance ignored this window and confronted MDHHS with a very brief (e.g. hours) review window.
5. In the view of the MDHHS, FACHEP at some stages was found to be not rigorous enough in pre-thinking how to translate their research findings into guidance for the community. This concerns individual situations where results were being shared with -for example- home owners without providing these results with a proper explanation of their meaning and guidance on how to deal with the situation at hand. Members of the FACHEP-team were also observed raising concerns over certain findings without presenting solutions or guidance to effectively deal with these concerns, or without consulting experts in public health communication.
6. Another point of concern raised by MDHHS is that different researchers from the FACHEP consortium do not seem to be on the same page, or speak with one voice. FACHEP meetings do not come up with a common message, since researchers are not on the same page and defending their right to their own positions on the grounds of academic freedom. There is limited preplanning of communication and responding to community questions raised by FACHEPs communication.
7. To MDHHS it is not at all clear what is being done in the research on water quality monitoring, and how FACHEP is dealing in this part of the research with quality assurance & interpretation, as well as communication.

Most information was gathered from the MDHHS and only limited time was available on day 3 of the scoping mission for a meeting with the Principal Investigator from the FACHEP team. Based on this meeting, KWR identified seven points of concern, which were shared by the Principal Investigator of FACHEP and two members of his staff at WSU, with regard to the project and the project oversight.

1. The initial perception of the FACHEP team was that, from the very beginning (Phase I), it was clear that 4.1-4.2 M$ was necessary to complete the project and that, for budgetary reasons, 3.1 M$ (+ 0.25 M$ after a 1st amendment) would be funded in 2016 and the remainder in 2017. In the beginning of 2017, it became clear that the remainder was not forthcoming. Because of extensive discussions on this item,

FACHEP felt that the contract was constantly being renegotiated, which did not help in the relationship with the client.

2. Because of the limited budget FACHEP cannot do all the research they promised to do. They feel very responsible to do what they can, especially towards the community. FACHEP said they would hire fewer people (project management, data analytics), sampling fewer homes, and conducting fewer analyses. They are retaining samples for possible analysis in the future.
3. FACHEP wants to do sound unbiased research, but is also aware of the difficult situation with regard to the public perception of the Flint water crisis. The legal situation creates a lot of pressure on the FACHEP team. Mr. McElmurry and Mr. Zervos were being called to testify on behalf of FACHEP. WSU/FACHEP never wanted the ongoing legal issues, which they feel are hampering their research. The project is under constant scrutiny from the public and the media, putting extra pressure on researchers and the legal department of Wayne State University, that is acting on behalf of FACHEP.
4. The PI for FACHEP feels that oversight by MDHHS is increasingly moving toward the exertion of influence on the research itself. According to the PI for FACHEP the State of Michigan at one point also threatened to limit funding for WSU for other non-FACHEP projects.[1]
5. FACHEP desired MDHHS involvement to complement the dataset on Legionella cases and even offered to fund it, thus relieving pressure on MDHHS resources. Moreover, FACHEP feels that they received no valid feedback from MDHHS during the 30-day review windows.
6. FACHEP wanted an independent panel to oversee their research from the beginning. However, FACHEP would not favor introducing it at this stage (aside from the regular peer review that FACHEP says they do conduct), given the fact that the project will soon be over and that the budget is limited. But if additional budgetary resources and time became available, they might be willing to renegotiate their review procedures.
7. FACHEP feels that there is an indisputable link between the change in the Flint water source and the Legionella outbreak, but senses that MDHHS thinks differently. FACHEP was aware of the discussion of missing onset data and the effect on the pre-crisis incidence. There was some dispute over this, but FACHEP feels that this would not affect the outcome of their research.

[1] The threat to limit funding for WSU is denied by the State of Michigan

# 3 Review of available information

## 3.1 General assessment

During the scoping mission a provisional evaluation of the Enhanced Disease Surveillance and Environmental Monitoring Project (FACHEP Phase II) in Flint, Michigan was made. This evaluation is based on the information about the project sent to KWR by MDHHS and shared by MDHHS during the scoping mission (see appendix II), available public information about the project and its context, as well as information provided by the principal investigator of the FACHEP team, Dr. Shawn McElmurry and his staff at Wayne State University.

### Basic conditions for project oversight are lacking

In a complex and extensive project such as FACHEP Phase II, that is working in a very sensitized community, one would expect to have a project management approach in place in which the roles and responsibilities of both client and contractor are clearly defined and the progress and outcomes of the project are constantly monitored with respect to the expected and agreed-upon deliverables and communication. Project management methods typically incorporate principles that ensure that checks and balances within a project are in place with regard to:

1. Continued business justification: will the project still deliver what it promised to deliver when it was started?

2. Continuous evaluation: does the project apply lessons learned to improve project performance?

3. Defined roles and responsibilities: is a clear organizational structure in place which acknowledges the role of the client?

4. Staged management: are complex projects broken down into subprojects and project phases with go/no go decisions to ensure proper project oversight and enable adjustments in case of changing circumstances?

5. Risk management: are project risks assessed and do project members know when and where to address these and/or address new risks that may emerge?

6. Clear deliverables: are the deliverables well defined, in terms of quality requirements, time, and money?

7. Communications: in the context of the Flint water crisis, the community and stakeholders are highly sensitive. Is there a clear communications strategy for the project and its outcomes?

Basic conditions for project oversight should include a contract and a project plan, in which the client and the contractor agree upon deliverables that the contractor will produce within

budget, time, quality constraints, etc., in conformity with the above principles, and taking into consideration the size and complexity of the project.

KWR was not able to do an in-depth assessment of the project management and project oversight. Most information was gathered from the MDHHS and only limited time was available for a meeting with the Principal Investigator from the FACHEP team. Our general impression of the FACHEP Phase II project, however, is that most of the conditions for proper project oversight are not in place.

- There is a contract (Contract #: 20163753-00, 8-16-2016), in the form of a grant agreement between MDHHS and Wayne State University (WSU, the Grantee), for Enhanced Disease Surveillance and Environmental Monitoring, Phase II – 2016. It stipulates the period of agreement (June 1, 2016 to December 31, 2017), funding ($3,100,000.00), and a Statement of Work (Attachment A in the contract).
- A first amendment (Contract #: 20163753-01, 12-9-2016) added $ 250,000.00 to the initial budget. The Statement of Work was modified.
- In May 2017 a revised Statement of Work was agreed upon. To both MDHHS and WSU this is the work plan that is currently in place. The revised work plan was laid down in a second amendment (Contract #: 20163753-002, 5-18-2017). Funding ($ 3,350,000.00) and the period of agreement were not changed. The revised Statement of Work is described in Attachment A of the contract (see Appendix III).

Both the initial and the revised Statements of Work give a general description of objectives, activities and expected outcomes. They do not, however, satisfy the basic conditions for project management and project oversight. For example, no milestones and deliverables (report, publications) are present. Moreover, it is not clear which budget is designated for the various objectives and activities. The contract only stipulates conditions for performance/progress reporting and financial reporting. Performance/progress reporting is specified in a general way in Attachment C of the contract (see Appendix IV). This attachment states that the contract manager shall evaluate reports submitted as described in Attachment C, items A and B, for their completeness and adequacy. Completeness and adequacy, however, have not been defined with sufficient specificity which basically makes it impossible to conduct project oversight in a satisfactory way.

The general judgement with regard to the seven principles mentioned for project management is summarized in the table below.

| # | PM Principle | Impression | Judgement |
|---|---|---|---|
| 1 | Business justification | During the scoping mission KWR was not able to generate a clear picture on where the project is in terms of project deliverables. There is no document available to describe the present situation. | Cannot be demonstrated |
| 2 | Continuous evaluation | There is unease and dissatisfaction of MDHHS with the project and the relationship with part of the FACHEP team. There are very few project progress reports and meetings between the FACHEP team and the client have | Cannot be demonstrated |

| | | | |
|---|---|---|---|
| | | been scarce. The reports and meeting minutes show no evidence of continuous evaluation. | |
| 3 | Roles / responsibilities | There is a FACHEP organisational structure. The role of the client is not clearly visible within this structure. As the client, MDHHS feels that there is too little coordination within the FACHEP team. | Available, client poorly defined |
| 4 | Staged management | The revised Statement of Work shows objectives A to K, general activities, and time frames, but no sub phases, budgets per activity, etc. | Subprojects defined, sub phases not clear |
| 5 | Risk management | A project risk register is not available. Risks have not been a regular agenda item of the meetings between FACHEP and MDHHS. | Cannot be demonstrated |
| 6 | Clear deliverables | Objectives, activities, expected outcome and measurements are only generally defined (i.e. quarterly written reports instead of measurable progress indicators) | Poorly defined |
| 7 | Communications | FACHEP works with a communications team and sends out press releases about the progress of their work. FACHEP also has a website. Part of their communications relate directly to the field of public health and are conducted by individual researchers and should therefore be brought into agreement with MDHHS. MDHHS has not defined a clear division of responsibilities for public health communication in the contract. | Needs a clear strategy |

### The current status of the project and circumstances surrounding the project do not help promote basic project oversight

The project has been running for about 1.5 years now. Mr. Richard Baird from the Governor's Office told us that the project with FACHEP was started in good faith. The Governor was seeking an independent research group that would look at the Legionella outbreak in Flint and produce a solid report, regardless of the outcome. This may be one of the reasons why the conditions for proper project oversight were not given sufficient attention, by either the Governor's Office or MDHHS.

The project has resulted in disagreements between the MDHHS and several of the FACHEP research organizations that are carrying out the research about the appropriate use of patient data, the appropriate epidemiological methodology, and communications. Mr. Shawn McElmurry, PI for the FACHEP project, said that the initial perception by the FACHEP team was that, from the very beginning (Phase I), it was clear that 4.1-4.2 M$ was necessary to complete the project and that, for budgeting reasons, 3.1 M$ would be funded in 2016 and the remainder in 2017. However, in early 2017 it became clear that the expected remainder was not forthcoming. Because of lengthy budgetary discussions that took long, FACHEP felt

that things were constantly being renegotiated, which did not help in their relationship with the client. Neither Mr. Baird nor MDHHS officials agree with this account.

The discussion then turned to the scientific meaning of the research results, primarily with regard to the research on epidemiology, and the translation of these results into guidance for the community. This deepened the dispute between the FACHEP researchers and MDHHS. The situation was then further aggravated by the lawsuit filed by the Attorney General's office against MDHHS officials for, among other things, obstruction of justice, following remarks made by MDHHS officials about FACHEP. This escalation of the dispute makes it almost impossible for the MDHHS to execute the oversight of (components of) FACHEP. The same will apply to any outside party that would perform project oversight on behalf of MDHHS or the Governor's Office. The PI for FACHEP said that the legal situation also places a lot of stress on the FACHEP team. Mr. McElmurry and Mr. Zervos were being called to testify on behalf of FACHEP. Furthermore the project is under scrutiny from the public and the media, putting extra pressure on researchers and the legal department of WSU. Given these circumstances, and in view of the fact that the project will end on December 31, 2017, and that, according to the FACHEP team, their budget is already constrained to the point that it probably won't be possible to perform all of the foreseen activities, means that any serious project oversight activity will probably amount to 'too little, too late'.

Consensus among FACHEP and MDHHS on the outcome of the research, as well as on its implications for public health, is currently lacking.

KWR did some basic reviewing of the existing research findings from the FACHEP project, and discussed them with experts from MDHHS and an expert from the University of Illinois at Chicago. This review process is described in Section 3.2 of this report, and more detailed reviews are provided in the appendices (Appendix V and VI). It would naturally benefit the research efforts addressing the Legionella outbreak in Flint in general, and the people of Flint in particular, if there were a consensus between FACHEP and MDHHS on the major research findings, and their implications for improving the control of *Legionella*, and thus prevent the recurrence of outbreaks such as those of 2014 and 2015. It is expected that the research results will become available at a yet unspecified time after the formal end of the project on December 31, 2017. It would obviously be disappointing if clear answers concerning the cause of the increased incidence of Legionnaires' disease in 2014 and 2015, and ways of preventing any recurrence, are not be provided. Nevertheless, this is a possible risk of conducting scientific research.

### 3.2 Scientific assessment

The assessment of the scientific quality of the FACHEP project *so far* (project ends December 31, 2017) proved to be difficult, due to the limited number of deliverables from the project that are currently available via MDHHS. The epidemiology research component has generated the largest output, and the KWR team has attempted to produce the best possible assessment of this material. In doing so, the team also had discussions with Dr. Samuel Dorevitch, Associate Professor of Environmental and Occupational Health Sciences at the University of Illinois at Chicago. More detailed results of this assessment can be found in Appendix V.

With regard to the epidemiology part of FACHEP, it can be concluded that:

(a) No information is available on progress of the prospective case-control study, but there are reasons for serious concern that it cannot be completed within the project period and thus may not provide meaningful results (see Appendix V). It appears that the realized number of cases during the project period is much lower than the number that was originally intended to be included in the study, and this must have major consequences for the statistical power of the analyses.
(b) The retrospective study of the 2014 and 2015 outbreaks appears to be completed and has resulted in a scientific paper of which a draft version has been sent to MDHHS. It is unclear whether this manuscript has been submitted to a scientific journal (as the 90 days contractual response time had passed, without comments from MDHHS due to the legal situation). The manuscript has raised serious comments and questions among members of the scoping mission and back office team (see Appendix V) which would need to be addressed to be capable of endorsing the conclusions. The message is clearly at variance with the conclusions from MDHHS's own analyses, which, while largely based on the same crude data, i.e. detailed case information from all GC cases in 2014-15, but not comparing with data from other counties, pointed to one of the Flint hospitals as the main source of *L pneumophila* infection, and thus characterized the outbreaks as (largely) "healthcare-associated". Main arguments are that 68% of the cases in the GC outbreaks of 2014-15 were not on Flint water at the home address, while the majority had been visited or been hospitalized in the same hospital and the end of the outbreak coincided with the installation of monochloramine disinfection of the water in the hospital plumbing system. Given its major impact and consequences, it would be of major importance to resolve this controversy. The more meticulous analysis of the cases exposure history by MDHHS and the methodology employed by MDHHS was more convincing than the analysis in the Zahran et al manuscript, but full endorsement of either of these studies would require access to the underlying data to evaluate and reproduce the analysis and conclusions.

With regard to the environmental microbiology, only one manuscript could be accessed, namely, that by B.G. Byrne et al. (see Appendix VI). This paper investigated the genetic diversity of *Legionella pneumophila* (the bacterium responsible for Legionnaire's disease) in Southeast Michigan, by comparing strains from Flint and Detroit residences (premise plumbing) with clinical isolates from hospitals within Michigan, as well as their infectivity and survival. The paper is logically organized, with a scientifically sound methodology. Some text seemed to suggest a link between the Flint water switch and the Legionella outbreak, though the study did not test or support this hypothesis. The choice of strains (i.e. their origin) could have been more thorough. The conclusions of the paper are justified by the data. Moreover, the paper may have important implications, since it points to the probability of underreporting pathogenic strains of *L. pneumophila*. This is due to the detectability bias that current urinary antigen tests have towards one specific serogroup of *L. pneumophila* (SG1), whereas other serogroups, although less frequently occurring, may be as virulent.

For the study on the occurrence of *Legionella* in residences and high risk facilities in Flint and "control areas", there were no data presented. The press release of FACHEP in the week of the scoping mission suggested that the target for the number of residences to be sampled was (almost) met in Flint and Genesee County outside of Flint, and not met in Wayne County. The press release gives an unbalanced (and hence suggestive) view, as only the Flint data are reported. The manuscript of Byrne et al states that the percentage of residences with Legionella positive samples in Flint and surrounding counties is similar. During the meeting with FACHEP, the PI indicated that the target of the high risk facilities was far from being met, only a few of these facilities were sampled. This raises concerns over the completeness of the evaluation of the role of residences versus high risk facilities as sources of Legionella

in Flint and neighbouring counties. The study on residences may still provide valuable links between Legionella occurrence in residences and other water quality parameters. The analysis are still underway.

Overall, the scientific output of the project is very limited thus far. The paper on environmental microbiology appeared scientifically sound and methodologically correct, whereas the publications on epidemiology seemed to draw conclusions that were not justified by the data, had flaws in methodology, and were lacking in scientific rigor. Apart from quality, the quantity of the work does not seem to correlate with the time and budget spent, nor does it appear to match the ambitions raised at the beginning of the project. However, more outcomes are expected, although it is not clear what the remaining scientific output of the project will be. Therefore final conclusions on this point cannot be drawn yet. The ambitions of FACHEP were not fully met, particularly in the case control study and the monitoring of Legionella in high risk facilities.

# 4 Conclusions and recommendations

## 4.1 General conclusions

The scoping mission performed by KWR has led to the following general conclusions regarding the FACHEP project and the oversight by MDHHS:

1. Basic conditions for project oversight are lacking. This makes proper project oversight almost impossible for the client or for any party that would represent the client.
2. The current status of the project and circumstances surrounding the project do not help promote basic project oversight.
3. Consensus among FACHEP and MDHHS on the outcome of the research, as well as on its implications for public health, is currently lacking.
4. The scientific output of the project that KWR has seen is very limited thus far, both with regard to quality and quantity. The quantity of the work does not seem to match the time and budget spent, nor does it appear to match the ambitions raised at the beginning of the project. However, more outcome is expected, so that final conclusions on this point cannot be drawn yet.

Despite all the good intentions underlying the establishment of FACHEP, the major problem is that there is no trust between the client and the contractor, and that the circumstances around the project (legal issues, constant attention from public and media) stand in the way of developing a climate where sound, unbiased and responsible research is promoted. The result is a project where the roles of research, communications, project management, and project oversight are completely unclear, and where there are different views, both based on scientific data, with regard to the relationship between the outbreaks of Legionnaires' Disease and the change in the Flint water source.

## 4.2 Recommendations

### Apply project management principles

In the event of an extension or follow-up of the research, KWR strongly recommends putting sufficient effort into the initial/definition phase of such a project in order to ensure that project management principles are put in place. This would include a set of clear agreements about the communications between the client and the contractor, the degree to which the client will be informed about the progress of the project and any possibilities of the client to influence decisions about next steps in the project.

KWR would be prepared and willing to do the project oversight on behalf of MDHHS, under the condition that the above mentioned issues will be addressed in a prolongation of the research. This prolongation comprises the renegotiation of the contract in which project management principles are put in place, roles are completely clear, and independent review of scientific research and public health communications is guaranteed.

## Consider reviewing scientific and public health communications

One of the most striking outcomes of the current mission is that client and contractor had different views on the central outcome of the FACHEP and their own research, based on the same data on the cases of legionellosis in 2014 and 2015 in Genesee county. FACHEP concludes that the 2014-2015 legionellosis outbreaks were likely caused by the changeover in drinking water supply, while MDHHS research clearly suggests that the outbreaks are healthcare-associated. The more meticulous analysis of the cases exposure history by MDHHS and the methodology employed by MDHHS was more convincing than the analysis in the Zahran et al manuscript, but full endorsement of either of these studies would require access to the underlying data to evaluate and reproduce the analysis and conclusions. KWR strongly recommends to resolve this issue by organizing a review of both scientific and public health communication. Regardless of the decision on continuation of the project and/or further financial support by the State of Michigan, such a review would be necessary to provide unequivocal information to the citizens and health professionals in the Flint region. Given the current societal tensions surrounding the issue, further confusion about the causes of the legionellosis outbreak and possible interventions would be highly undesirable.

Ideally, MDHHS and FACHEP should both submit their data and analysis to a scientific review by independent international reviewers, in order to resolve the apparent dispute on the cause of the 2014-2015 outbreak and the implications of the research for prevention of legionellosis and actions by the community and healthcare professionals. Within such a review, all researchers involved should jointly exchange all existing data (mainly epidemiology) in order to reach consensus on the cause of the outbreak and the implications for legionellosis prevention. A clear strategy for communication of the results needs to be designed.

KWR is also willing and prepared to organize such a review.

# Appendix I Short description of KWR investigators

## Key staff of KWR and Utrecht University involved in scoping mission

### Participants in scoping mission

**Dr. Anthony Verschoor MSc** is researcher within the team Microbial Water Quality and Health. Anthony is educated within aquatic ecology and water quality and has performed his PhD research on microalgae. Apart from ecology, Anthony has further developed into (environmental) biotechnology and water technology. Over the past years he worked on the use of aquatic organisms for water treatment, biomass production and resource recovery. Anthony is specialist in microbial ecology, biological stability, surface water quality and closing cycles (circular economy).

**Dr. Gert Doekes (University Utrecht)** is assistant professor and senior staff member of the division Environmental Epidemiology, Institute for Risk Assessment Sciences (IRAS) of the University Utrecht. His research activities have focused on exposure assessment for biological agents (microbial agents like endotoxins, fungal pro-inflammatory agents, and allergens) in the home and work environment, and use of serologic and other immunological methods to assess health effects in population studies on asthma and allergy. He is coordinator of the EU-funded six laboratories collaborative project on optimization of airborne allergen measurement in the work environment (MOCALEX, 2002-2005).

Participation in national and international research projects, e.g. various EU-funded multi-center population studies on occurrence and development of allergic diseases (PARSIFAL, PASTURE, EFRAIM, HITEA), in which IRAS took responsibility for analyses of environmental samples from homes or on farms of participants.

Co-author and internal reviewer for >70 papers from these and related projects. In addition: reviewer of papers for journals in the areas of Allergy, Lung Diseases, and Environmental Health Research. Member of the Editorial Review Board of Environ Health Perspectives.

**Prof.dr. Gertjan Medema** is the chief science officer and principal microbiologist. He is also part-time chair on Water & Health at Delft University of Technology. As chief science officer he coordinates the joint research programme of the Dutch water utilities (BTO) and the research strategy and environment at KWR. He is an internationally recognized expert and scientific coordinator of the WHO collaborating centre on Water Quality and Health, active in the WHO working group on microbiology; advisor of EU DG Environment on water reuse guidelines, IWA fellow and (past) chair of the specialist group on Health-Related Water Microbiology; member of the Dutch Health Council Committee on safe bathing water.

**Loet Rosenthal MSc** is Manager Water Quality and Health and member of the Management Team at KWR Watercycle Research Institute. Loet has 25 years of experience in the water industry. Loet is responsible for coordination of national and international research activities aimed at understanding and influencing water quality and health issues within the watercycle. He is responsible for KWR's leading chemical and microbiological laboratories and for KWR's role as WHO Collaborating Centre on Water Quality and Health and accredited test laboratory for household water treatment systems. On behalf of KWR Loet manages relations with water utilities, governments, laboratories and other mostly public partners. Until he assumed his position at KWR in 2017 Loet was Director of Water Supply at PWN Water Company North-Holland, a public utility providing drinking water to about 1,7 million residents and businesses. In his 15 years at PWN he was responsible for setting up an ISO 55.001 certified asset management system. Under his supervision an extensive investment program aimed at securing a robust water supply system for the next decades was carried out. Loet holds a master's degree in Civil Engineering with a specialization in Sanitary Engineering.

### Experts participating in Back office

**Dr. Paul van der Wielen** is principal scientist in drinking water microbiology. Paul's expertise is in microbial regrowth in drinking water, biological stability, microbial quality in drinking water, industry water and water used in horticulture, *Legionella*, *Pseudomonas aeruginosa,* nontuberculous mycobacteria, and fungi. In addition, he is involved in biological processes of drinking water purification, nitrification, biological iron removal, biological demagnetisation, next generation sequencing, multilocus sequence-based typing, quantitative PCR, AOC method, methods to determine biological stability, biofilm interactions, biofilm measurements, growth-enhancing properties and materials in contact with drinking water.

**Prof. dr. Annemarie van Wezel** (MSc in Biology, PhD in Environmental Chemistry and Toxicology) has 25 years' experience as a scientific researcher in risk assessment, toxicology and environmental chemistry, and environmental policy assessment. She has published over 45 papers in peer-reviewed scientific journals. She is experienced in working closely with the political process and interacting with the press. Annemarie also has experience in leading complex interdisciplinary research projects and has successfully headed research-group collaborations involving up to 60 people. She is a member of the Dutch Board for the Authorisation of Plant Protection Products and Biocides, and of the Dutch Health Council. She is chair (as per rotation) of the Crisis Expert Team Environment and Drinking Water.

**Prof. dr. Bert Brunekreef MSc (University Utrecht)** is professor of Environmental Epidemiology and Director of the Institute for Risk Assessment Sciences (IRAS)

Bert Brunekreef has an academic education in Environmental Sciences at the University of Wageningen, the Netherlands, 1971-1979. From 1979-2000, he has been employed by the Department of Environmental Health of the Wageningen University, first as assistant professor, since 1986 as associate professor, and since 1993 as full Professor. In 1985, he obtained his Ph.D. degree in Environmental Epidemiology from the University of Wageningen.

In 1986/1987, he spent the academic year at the Harvard School of Public Health, studying health effects of air pollution episodes, and of living in damp homes.In 1995, he served as the main organizer of the annual ISEE/ISEA conference which was held in the Netherlands that year. In 1998, he was chosen to be president of the ISEE for the years 2000 and 2001.

Since the early 1990s, prof. Brunekreef has coordinated five EU funded studies (PEACE, TRAPCA, AIRALLERG, AIRNET and ESCAPE) in the field of air pollution, allergy and health. He is or has been partner in many other international collaborative studies. He has also been the PI on two studies funded by the US Health Effects Institute.

In 2000, his Wageningen Department was moved to Utrecht University where it merged with the existing RITOX Institute to create the 'Institute for Risk Assessment Sciences (IRAS)'. In 2005 IRAS absorbed the Veterinary Public Health Department, and prof. Brunekreef is Director of IRAS since January 1, 2005. IRAS has currently about 130 employees.

Prof. Brunekreef is Professor of Environmental Epidemiology in both the Faculties of Veterinary Medicine, and the Faculty of Medicine at the Utrecht University. On several occasions, Bert Brunekreef served as advisor on national and international panels in the field of environmental health, including the Dutch National Health Council, of which he is a member, WHO and the US EPA. He is co-author of more than 500 peer reviewed journal articles in the field of environmental epidemiology and exposure assessment. In recent years, he received the ISEE John Goldsmith award (2007), the European Lung Foundation Award (2007), an honorary doctorate of the Catholic University of Leuven, Belgium (2008), the Heineken Prize for Environmental Sciences (2008), and an Academy Professorship of the Dutch Royal Academy of Sciences (2009) to which he also was elected to become a member in 2009.

**Dr. Laurens Hessels** researches knowledge and innovation. He advises organisations in the water sector about knowledge management, learning processes and implementation of research results. He also contributes to the KWR research strategy, the design of its research programmes and collaboration with knowledge partners. Laurens studied environmental chemistry and philosophy of science in 2010 and completed his PhD in 2010 with a study into how university researchers deal with the practical applications of their work. From 2010 to 2016, Laurens worked at the Rathenau Institute, where he did research into coordination, public-private collaboration and international knowledge networks. He also did temporary work at the Ministry of Education, Culture and Science for a year to contribute to the 2025 Vision for Science.

**Idsart Dijkstra MSc MBA** has developed 23 years of experience in the field of water supply and sanitation, of which 3 years abroad. He managed several research projects on drinking water supply, waste water treatment and solid waste. Through his international assignments, he is duly acquainted with the preparation and implementation of water supply and sanitation projects abroad. During his long-term assignments in Nicaragua, he acquired experience in project management and the preparation and implementation of training programs in particular. He is fully conversant with the managerial and organizational aspects of effective and efficient utility management and the requirements for adequate institutional frameworks for the water sector.

For a mayor part of his professional career Idsart Dijkstra worked at the largest Dutch drinking Water Company 'Vitens'. In the position of Senior Process Technologist he was involved in many projects and optimizations of drinking water plants. From end 2009 until beginning 2012 Idsart Dijkstra worked at Vitens-Evides International in the position of Project Director and amongst others responsible for the projects in Mozambique, South Africa, Suriname and Bolivia.

Since 2012 Idsart Dijkstra is working at KWR at the Department of Water Systems and Technology at KWR Watercycle Research Institute in the position of head and member of the

Management team. He oversees a department of 75 researchers on water technology and geo/eco-hydrology. His focus is on closer cooperation in the Dutch water sector as well as the international market in the years to come. The topics are amongst others: Managed Aquifer Storage and Recharge, Water in the Circular Economy, Advanced Water Treatment Technology, SMART Distribution networks.

Idsart Dijkstra holds a master's degree in Civil Engineering (1992) with a specialization in Sanitary Engineering from Delft University of Technology and an MBA (2008) from Rotterdam School of Management (Erasmus University).

**Nellie Slaats MSc** is a team leader of the Water Infrastructure team and project manager of the projects this team carries out. The Water Infrastructure team consists of fifteen people and these people work on a wide range of topics within drinking water distribution, such as the development of tools for the conservancy and maintenance of the pipeline network, the water quality in the pipeline network, the optimisation of designs for new pipeline networks, modelling consumption patterns and installing sensors. Nellie has a background in chemistry at Utrecht University and specialises in the interaction of drinking water with pipeline materials. As Project Coordinator and Project Manager, he is involved in national and international collaborative projects.

# Appendix II List of files shared by MDHHS

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|---|---|---|---|---|
| KWR1\EGRAMS | 20163753-02_Wayne State EDSEM Amendment 2.pdf | 14-Jul-2017 | 08:38 | 99591 |
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| KWR1\WSU IRB | Complete IRB package submitted March 7_ 2017.pdf | 31-Mar-2017 | 16:50 | 12061842 |
| KWR1\WSU IRB | IRB067016B3E_Amendment Submitted to WSU IRB 23 March2017.pdf | 31-Mar-2017 | 16:55 | 1051573 |
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| KRW3a\Original Submission 1 | 2. Appendix Listing of Health Facilities.docx | 25-Jul-2016 | 17:07 | 57543 |
| KRW3a\Original Submission 1 | 3. Legionellosis Case Information Form.docx | 25-Jul-2016 | 17:07 | 207010 |
| KRW3a\Original Submission 1 | 4. DCH-1294_Data Use Agreement.rtf | 25-Jul-2016 | 17:12 | 520336 |
| KRW3a\Original Submission 1 | 5. DUA Appendix_MDSS_Basic Intake and Legionellosis Data Elements.docx | 25-Jul-2016 | 17:07 | 16446 |

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| KRW3a\Original Submission 1 | 7. FACHEP Overview_Control of Legionnaires' Disease_Upd 7 24 v5.pptx | 25-Jul-2016 | 17:07 | 163825 |
| KRW3a\Original Submission 1 | 8. Pre Post Community Presentation Survey.docx | 25-Jul-2016 | 17:07 | 13741 |
| KRW3a\Original Submission 1 | 9 12 16 letter from GCPO Re PO (00050546xBFCFF).doc | 14-Oct-2016 | 14:47 | 198144 |
| KRW3a\Original Submission 1 | 9. Updated Clinical Guidance for Legionella_25 July.docx | 25-Jul-2016 | 17:07 | 48506 |
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| KRW3D1 | FACHEP Enhanced Surveillance Informed Consent-V3-clean.pdf | 15-Aug-2016 | 22:21 | 115978 |
| KRW3D1 | FACHEP Enhanced Surveillance Informed Consent-V3-with_marks.pdf | 15-Aug-2016 | 22:23 | 119748 |
| KRW3D1 | FACHEP Summary_Education Clinical Surv Outreach and Support-V2.docx | 5-Aug-2016 | 09:59 | 19054 |
| KRW3D1 | FACHEP-MDHHS_Data Use Agreement_Fully Signed.pdf | 10-Aug-2016 | 13:59 | 4396390 |
| KRW3D2 | Initial_Review_Application_239579_7-FACHEP_EPI.doc | 9-Aug-2016 | 00:45 | 111616 |
| KRW3D2 | Initial_Review_Application_239579_7-FACHEP_HOUSEHOLD.doc | 12-Jul-2016 | 22:05 | 109056 |
| KRW3D2 | Introductory Script of FACHEP Team to Legionellosis Case or Case Proxy.pdf | 15-Aug-2016 | 22:00 | 74497 |
| KRW3D2 | IRB#067216B3E-HouseholdMonitoring.pdf | 7-Jul-2016 | 17:05 | 58978 |
| KRW3D2 | Phase 2 Project Narrative_clin ed_epi_surv_25 July cleaned.docx | 25-Jul-2016 | 17:06 | 68683 |
| KRW3D2 | Phase2ProjectNarrative v20-wAppendix.pdf | 10-Aug-2016 | 16:39 | 5829857 |
| KRW3D2 | Phase2ProjectNarrative-Draft19-wAppendix.pdf | 9-Aug-2016 | 01:01 | 5773234 |
| KRW3D2 | Response to MDHHS comments from Monday Aug 1.docx | 3-Aug-2016 | 18:07 | 23429 |
| KRW3D2 | WSU_IRB#067016B3E-EnhancedSurveillance-stamped.pdf | 3-Aug-2016 | 18:06 | 7176748 |
| KRW4ai | AEESP  MSwanson June 2017.pdf | 16-Jun-2017 | 08:36 | 5022292 |
| KRW4ai | ASM LB Poster copy.pdf | 30-May-2017 | 07:02 | 3203866 |
| KRW4ai | FACHEP Legionella Figures 1-6.pdf | 18-May-2017 | 16:53 | 3063658 |
| KRW4aii | 1 DRAFT SIGMA Unit Code Lookup by Employee Name.xlsx | 5-Oct-2017 | 11:20 | 184317 |
| KRW4aii | FACHEP-MDHHS Webex 8 March 2017.pdf | 9-Mar-2017 | 15:29 | 2732146 |
| KRW4aii | FWICC_Meeting_FACHEP_Presentation1-July_8_2016_528953_7.pdf | 8-Aug-2017 | 11:33 | 1082206 |
| KRW4aii | MSwanson lab manuscript 9-23-17.pdf | 23-Sep-2017 | 14:58 | 2529554 |
| KRW4aii | Prep Summit Template_3.22.17.pdf | 23-Mar-2017 | 14:41 | 2704520 |
| KRW4aii | Prep Summit Template_4.18.17.pdf | 18-Apr-2017 | 22:35 | 2640547 |
| KRW4bi | Flint Town Hall 5-9-17.m4a | 9-May-2017 | 19:09 | 14026123 |
| KRW4bii | Flint FACHEP May 2017.ppt | 12-May-2017 | 12:40 | 5033472 |
| KRW4c\Products 3 | 062917FACHEPmeeting.pdf | 4-Oct-2017 | 11:02 | 120817 |

| | | | | |
|---|---|---|---|---|
| KRW4c\Products 3 | A Retrospective Study of Legionnaires Disease 06_08_2017.docx | 8-Jun-2017 | 11:25 | 129371 |
| KRW4c\Products 3 | Confirming messaging from Monday presentation.pdf | 4-Oct-2017 | 11:07 | 92939 |
| KRW4c\Products 3 | FACHEP Figure legends.docx | 18-May-2017 | 16:53 | 176961 |
| KRW4c\Products 3 | FACHEP Talking points.docx | 5-Dec-2016 | 17:16 | 35169 |
| KRW4c\Products 3 | FlintMAY9Release-FINAL-050817_2140.docx | 9-May-2017 | 10:42 | 16121 |
| KRW4c\Products 3 | flintswanson ms.docx | 6-Jun-2017 | 12:35 | 16474 |
| KRW4c\Products 3 | Legionella Abstract May 2017.docx | 18-May-2017 | 16:53 | 125156 |
| KRW4c\Products 3 | Perry_et_al_Sustaining Life in an Anthropogenic Crisis.pdf | 17-Apr-2017 | 15:20 | 64114 |
| KRW4c\Products 3 | PoU Filter study_PressRelease_May8_FINAL.docx | 16-Jun-2017 | 17:38 | 18796 |
| KRW4c\Products 3 | press release flint water 317.pdf | 14-Jul-2017 | 10:19 | 362462 |
| KRW4c\Products 3 | SEMEC Agenda 9-2017 RSVP.doc | 12-Sep-2017 | 17:57 | 28160 |
| KRW4c\Products 3 | Steno Abstract.pdf | 13-Mar-2017 | 12:19 | 90361 |
| KRW4c\Products 3 | Update and Collaboration Meeting_3 Feb 17.pptx | 3-Feb-2017 | 15:14 | 132091 |

# Appendix III Attachment A

*Attachment A from: Contract #: 20163753-002. Amendment No. 2 to the Agreement Between the Michigan Department of Health and Human Services and Wayne State University for Enhanced Disease Surveillance and Environmental Monitoring, Phase II – 2016.* Page 1 of 4.

Attachment 1- HIPAA Business Assoicate Agreement Addendum

**Attachment A - Statement of Work**

| | |
|---|---|
| **Objective :** | A: This critical activity of the FACHEP project focuses on providing technical and logistical support to ensure control of Legionellosis in Flint and Genesee County. |
| **Activity :** | 1: The following activities will be conducted as part of this FACHEP component focused on disease education and control: 1) Pneumonia and LD focused Clinician Engagement in Flint & GC; 2) Investigation Support & Family Visits, Flint/GC; 3) Control population HH & Family Interviews; and 4) LD Surveillance System Evaluation. |
| **Responsible Staff :** | Dr. Paul Kilgore, MPH,MD |
| **Date Range :** | 06/01/2016 - 03/31/2017 |
| **Expected Outcome :** | This critical activity is expected to generate trust among Flint and Genesee county residents around awareness, understanding and education for Legionellosis and pneumonia. This activity is expected to strengthen City-level and county-level expertise among health-care providers for the screening, identification, diagnosis, treatment and reporting of suspected Legionellosis among Flint and Genesee county residents. |
| **Measurement :** | Qualitative and quantitative metrics will be ascertained on a continuous basis during the 2-year project period with the goal of a) describing patterns of clinical pneumonia and Legionellosis among Flint and Genesee county residents; b) describing patterns of clinical pneumonia and Legionellosis among a control population of similar sociodemographic characteristics; c) evaluating the quality of Legionellosis surveillance performed in Flint, Genesee county and the control population with similar characteristics. |
| **Objective :** | B: To conduct a rigorous study designed to quantify the prevalence and virulence of Legionella spp in residential dwellings, health-care facilities, and associated water distribution systems. |
| **Activity :** | 1: Collect and analyze water and biofilm samples from within water distributions systems in Flint and associated controls during multiple times of the year. |
| **Responsible Staff :** | Shawn P. McElmurry, Ph.D. |
| **Date Range :** | 06/01/2016 - 12/31/2017 |
| **Expected Outcome :** | The prevalence of Legionella spp. in potable water systems and the virulence of L. pneumophila within Flint will be defined. How these numbers compare to other locations and vary in Flint during peak and off-peak seasons will also be characterized. Biochemical factors likely that are associated with increased levels of L. pneumonphila will be identified. The relationship between chlorine residue and presence of Legionella spp. in public water systems will provide guidance for maintaining adequate chlorine levels necessary to reduce the risk of exposure to legionella within municipal water systems. |
| **Measurement :** | The prevalence of Legionella will be defined in statistically representative samples from within the Flint water distribution system, within Genesee County adjacent to Flint and within another comparable city. |
| **Objective :** | C: To enhance communication, community engagement and address social determinants of health to optimize understanding and appropriate behavioral response of residents to Legionnaires' Disease. |
| **Activity :** | 1: Development of a proactive communications program, engagement activities and focused interventions that leverage existing social resources. |
| **Responsible Staff :** | Matthew Seeger, Laura Sullivan & Joanne Sobeck |
| **Date Range :** | 06/01/2016 - 12/31/2017 |
| **Expected Outcome :** | Enhanced community-level coordination, community participation, communication and sustained development of adaptive behaviors that improves health knowledge of Legionnaires' Disease and enhances trust among residents. |
| **Measurement :** | Reduced time from symptom onset to case notification as a result of greater resident understanding, engagement and trust; number of households reporting normal use of household water supply in accordance with guidelines and recommendations; number of residents participating in engagement and communication activities, number of residents provided social support |
| **Objective :** | D: Communication support as described in section 4 of IRB approved protocol. |
| **Activity :** | 1: Provide technical communication support to city, county, state and federal officials to facilitate optimal communication of risk and project results. |
| **Responsible Staff :** | Matt Seeger |
| **Date Range :** | 04/01/2017 - 12/31/2017 |



Final

*Appendix III: Attachment A, Page 2 of 4.*

| | |
|---|---|
| **Expected Outcome :** | Enhanced coordination among official sources and greater communication capacity. |
| **Measurement :** | Monthly list of presentations and events as described in Section 4.8 of the IRB approved protocol. |
| **Activity :** | 2: Assist with the development of educational programs to raise citizen awareness of Legionellosis and project messaging/outreach. |
| **Responsible Staff :** | Matt Seeger |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Enhanced coordination among official sources and greater communication capacity. |
| **Measurement :** | Monthly list of presentations and events as described in Section 4.8 of the IRB approved protocol. |
| **Objective :** | E: Community Engagement/Education as described in Task 2.1.1.2A in IRB approved protocol document. |
| **Activity :** | 1: Establish and support collaborative educational programs to raise citizen awareness of Legionellosis. |
| **Responsible Staff :** | Ben Pauli |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Educate community residents and forward-looking health programs in which residents have clear sense of ownership. Improved health knowledge, lower levels of misunderstanding, and reduced risk of Legionellosis. |
| **Measurement :** | Monthly Number of education events held and Annual results of pre-post knowledge tests (as described in IRB approved protocol 2.1.5) |
| **Objective :** | F: Community-based household evaluation of social-behavioral evaluation to support Legionnaires' disease prevention and control in Flint as described in Section 2.2 of the IRB approved protocol document. |
| **Activity :** | 1: Train and supervise interview teams and community navigators to conduct standardized household surveys. |
| **Responsible Staff :** | Joanne Sobeck |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Increased utilization of programs by Flint residents' that will result in enhancements in resident health and well-being. |
| **Measurement :** | Tabular report on aggregate household and residential characteristics, health and social behavioral variables and results of household water sampling as described in 2.5.5 of IRB approved protocol document. |
| **Activity :** | 2: Identify residents' needs and share information regarding resources available to Flint residents that help improve their health and well-being |
| **Responsible Staff :** | Joanne Sobeck |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Increased utilization of programs by Flint residents' that will result in enhancements in resident health and well-being. |
| **Measurement :** | Tabular report on aggregate household and residential characteristics, health and social behavioral variables and results of household water sampling as described in 2.5.5 of IRB approved protocol document. |
| **Objective :** | G: Legionellosis–focused clinician engagement in Flint and Genesee County as described in Task 2.1.1.2B in IRB approved protocol document. |
| **Activity :** | 1: Provide expert technical support to health-care providers that enables early diagnosis, treatment and reporting of all residents in Flint and Genesee County who are suspected of being infected with Legionella based on state-of-the-art clinical and laboratory practices. |
| **Responsible Staff :** | Marcus Zervos |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Reduced numbers of cases and deaths associated with Legionnaires' disease at or below rates found over previous 10 years. Enhanced coordination among medical professionals. |
| **Measurement :** | Number of education and engagement events, number of providers engaged, and number of providers participating in MiHAN (as described in IRB approved protocol 2.1.5). |

Appendix III: Attachment A, Page 3 of 4.

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|---|---|
| **Activity :** | 2: Clinical evaluation of Legionellosis cases in Genesee County and consultation to optimize evaluation and treatment of reported cases, as well as prevention of additional cases. |
| **Responsible Staff :** | Marcus Zervos |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Reduced numbers of cases and deaths associated with Legionnaires' disease at or below rates found over previous 10 years. Enhanced coordination among medical professionals. |
| **Measurement :** | Number of education and engagement events, number of providers engaged, and number of providers participating in MiHAN (as described in IRB approved protocol 2.1.5). |
| **Objective :** | H: Prospective Case-Control - Legionellosis case-patient, cluster and case-control outbreak investigation in Flint/Genesee County as described in Section 2.4 of IRB approved protocol document. |
| **Activity :** | 1: Provide hospital- and community-based technical support to hospitals, for rapid, efficient and complete case-patient and proxy interview, data collection and preliminary analysis of exposures relevant to assess risk of Legionnaires' disease among Flint residents. |
| **Responsible Staff :** | Paul Kilgore |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Clinical case series description and analysis of case control study data describing factors associated with Legionellosis. |
| **Measurement :** | Quarterly summary of case and control enrollment and demographics and numbers of presentations provided. Annual report as described in sections 2.4.2.3 and 2.4.2.5 of IRB approved protocol document. |
| **Activity :** | 2: Provide technical support and coordination of household and facility environmental investigations to facilitate efficient and accurate water sample collection for Legionella pneumophila testing. |
| **Responsible Staff :** | Paul Kilgore |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Clinical case series description and analysis of case control study data describing factors associated with Legionellosis. |
| **Measurement :** | Quarterly summary of case and control enrollment and demographics and numbers of presentations provided. Annual report as described in sections 2.4.2.3 and 2.4.2.5 of IRB approved protocol document. |
| **Activity :** | 3: Provide technical support of the MDSS and county level surveillance systems to determine if they can adequately capture cases to rapidly detect outbreaks in Legionellosis. |
| **Responsible Staff :** | Paul Kilgore |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Clinical case series description and analysis of case control study data describing factors associated with Legionellosis. |
| **Measurement :** | Quarterly summary of case and control enrollment and demographics and numbers of presentations provided. Annual report as described in sections 2.4.2.3 and 2.4.2.5 of IRB approved protocol document. |
| **Objective :** | I: Retrospective Analysis of existing Legionnaire's Disease data as described in Section 2.3 of IRB Approved protocol document. |
| **Activity :** | 1: To apply standard US CDC methodologies to describe the Legionellosis surveillance system in Flint, Genesee County and comparison areas of Oakland and Wayne Counties. Our hypothesis during these evaluations is that the MDSS and county level surveillance systems adequately capture cases to rapidly detect outbreaks in Legionellosis. |
| **Responsible Staff :** | Sammy Zahran |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Describe relationship between chlorine residue and presence of Legionella spp. in public water systems. Define distribution of Legionella spp. in potable water as well as water distribution systems in and around Flint. |
| **Measurement :** | Quarterly written reports describing ongoing results of statistical data analysis, presentation given as described in Section 2.3.5 of IRB approved protocol document. |
| **Activity :** | 2: Evaluate if the incidence of Legionellosis is associated with changes in water quality. |

Appendix III: Attachment A, Page 4 of 4.

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|---|---|
| **Responsible Staff :** | Sammy Zahran |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Describe relationship between chlorine residue and presence of Legionella spp. in public water systems. Define distribution of Legionella spp. in potable water as well as water distribution systems in and around Flint. |
| **Measurement :** | Quarterly written reports describing ongoing results of statistical data analysis, presentation given as described in Section 2.3.5 of IRB approved protocol document. |
| **Activity :** | 3: To identify practical opportunities for improving Legionnaires' disease surveillance in the city of Flint and elsewhere that support sustainable and high-quality case-patient reporting from health-care providers and facilities to the MDSS. |
| **Responsible Staff :** | Sammy Zahran |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Describe relationship between chlorine residue and presence of Legionella spp. in public water systems. Define distribution of Legionella spp. in potable water as well as water distribution systems in and around Flint. |
| **Measurement :** | Quarterly written reports describing ongoing results of statistical data analysis, presentation given as described in Section 2.3.5 of IRB approved protocol document. |
| **Objective :** | J: Legionella-focused water quality assessment of residential units and high-risk facilities as described in section 3 of the IRB approved protocol document. |
| **Activity :** | 1: Coordinate the deployment of trained, multi-disciplinary sampling teams |
| **Responsible Staff :** | Shawn McElmurry |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Characterize how critical water quality parameters relate to the presence of legionella bacteria in residential, facility, and municipal water systems. |
| **Measurement :** | Number of education events and results of prevalence study provided on a quarterly basis. Annual report comparing values in Flint to other communities. As described in sections 3.2.6 and 3.3.5 of the IRB approved protocol document. |
| **Objective :** | K: Determination of L. pneumophila diversity among environmental and clinic isolates as described in Section 3.4 of the IRB approved protocol. |
| **Activity :** | 1: Collect environmental samples in support of Legionellosis outbreak investigation. |
| **Responsible Staff :** | Michelle Swanson |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Characterize strains of L. pneumophila and associations between clinical and environmental isolates. |
| **Measurement :** | Report genetic composition of isolates to public health agencies as available. |
| **Activity :** | 2: Determine L. pneumophila diversity among clinical and environmental isolates. |
| **Responsible Staff :** | Michelle Swanson |
| **Date Range :** | 04/01/2017 - 12/31/2017 |
| **Expected Outcome :** | Characterize strains of L. pneumophila and associations between clinical and environmental isolates. |
| **Measurement :** | Report genetic composition of isolates to public health agencies as available. |

# Appendix IV Attachment C

*Attachment C from: Contract #: 20163753-002. Amendment No. 2 to the Agreement Between the Michigan Department of Health and Human Services and Wayne State University for Enhanced Disease Surveillance and Environmental Monitoring, Phase II – 2016.* 1 page.

**ATTACHMENT C**

**PERFORMANCE / PROGRESS REPORT REQUIREMENTS**

A. The Grantee shall submit the following:

A list of upcoming and completed presentations and publications is required as a supplemental report at the time of the submission of the Financial Status Report. This list should be sent to Dr. Eden Wells at wellse3@michgian.gov.

B. Any such other information as specified in the Statement of Work, Attachment A shall be developed and submitted by the Grantee as required by the Contract Manager.

C. All other reports and information shall be submitted to the Contract Manager at:

http://egrams-mi.com/dch

D. The Contract Manager shall evaluate the reports submitted as described in Attachment C, Items A. and B. for their completeness and adequacy.

E. The Grantee shall permit the Department or its designee to visit and to make an evaluation of the project as determined by Contract Manager

# Appendix V Epidemiology assessment

## Preliminary scientific assessment of FACHEP epidemiological studies

According to the FACHEP Phase II Project Description*), epidemiological studies would comprise:

A) A retrospective analysis of all LD cases reported in the period 2011-2016 in Genesee Country, and, for comparison Wayne County and Oakland County, to assess major risk factors, and particularly the association with the switch in drinking water regime in 2014-15 in Flint (p.19: 2.1.2.G-H; p.22: 2.3.1.2F, 2.3.2.A; p.23: 2.3.2.-D)

B) A prospective case-control study with new cases reported in GC during the study period compared to matched controls – either hospital based, or residential controls (p.27: 2.4.1.2.E12-14; p.29: 2.4.2).

**) There is a lack of clearly defined activities summarized in work packages with clear deliverables. As indicated: information for points A) and B) is collected from several paragraphs and pages in the project description.*

### Retrospective analyses (A)

Activity A) has been completed summer 2017, resulting in a (submitted?) scientific paper by *Zahran et al*. The MS concludes that the LD outbreaks of 2014-15 in GC were definitely due to the water regime change; arguments are based on statistical analyses comparing case incidences in census tracts in or outside Flint (including census tracts in the other counties) and in weeks before or during the water regime switch period in Flint, and some additional supporting analyses on relations with free chlorine concentrations.

The message is clearly at variance with the conclusions from MDHHS's own analyses, which, while largely based on the same crude data, i.e. detailed case information from all GC cases in 2014-15, but not comparing with data from other counties, pointed to one of the Flint hospitals as the main source of *L pneumophila* infection, and thus characterized the outbreaks as (largely) "healthcare-associated". Main arguments are that:

- 68% of the cases in the GC outbreaks of 2014-15 had not been on Flint water at the home address
- 59% of these cases had healthcare exposure (defined as any inpatient, outpatient, or visitor contact with a Genesee County hospital during the patient's incubation period).
- the outbreak of 2015 ended weeks before the switch back to Detroit water, and started to decline after thermal treatment and the installation of monochloramine disinfection of the water in the hospital plumbing system.

Given its major impact and consequences, it would be of major importance to resolve this controversy. The submitted paper by the FACHEP consortium appears to have applied a more thorough and extensive stat analysis, but raises a number of serious critical questions with regard to the applied methodology, and gives little insight in the actual crude numbers in the various analyses. A thorough analysis and comparison of the FACHEP manuscript and the MDHHS reports would however require considerable extra efforts, e.g. by an independent expert panel with unlimited access to all relevant crude data used in the two investigations, the statistical procedures applied, etc. – which was not within the scope of the current mission.

### Prospective study (B)

The Phase II project proposal is not clear with regard to the precise objectives of this part of the study. Part 2.4 apparently focuses on future outbreaks (during the study period) and aims to evaluate and approve outbreak surveillance and control measures, while at the same time comparing LD incidence in GC (incl. Flint) with LD incidence in Oakland county, and assessing and comparing risk factors in these coming outbreaks. Controls however would be from GC only (page 27, E.12-14). According to page 29, (2.4.2 E,F) FACHEP also intended to assess the relative risk of LD in GC "compared with residents living in control populations" …. "to provide insight to residents and health-care providers on strategies for disease prevention".

Apart from the lack of clearly defined target and study populations, the proposal neither mentioned numbers of cases and controls that the researchers expected to include. For investigational methods (page.27, E.12) they refer to a table for power calculations from a standard textbook (page 28), with case numbers varying from 43 to 137 and controls from 213-558. Given the sharp drop in LD incidence after 2015, however, the number of reported LD cases in GC during the FACHEP Phase II study period would remain (far) below the lowest of these figures.

No information on progress in this part of the project has been obtained before or during the scoping mission – it is unknown how many cases and controls have been included thus far, but given the above considerations it seems highly unlikely that there are (or will be within a few months) sufficient numbers for meaningful statistical analyses.

We thus conclude that:

- the FACHEP proposal as granted lacked a clear objective for this part of the study, an indication of the planned size of the case-control study population, nor the period in which cases and controls should be enrolled and analyzed;
- the investigators thus far did not report such numbers;
- it remains unknown whether this part of the project makes sufficient progress, or has the potency to produce meaningful results before the end date of the project.

### Reviewers' comments and questions: epidemiology and public health research

Evaluation of the scientific quality of the epidemiological studies is hampered by the lack of a clearly structured project plan. The FACHEP Phase II proposal mentions a number of activities – some are actually occurring repeatedly in various paragraphs - without giving specific details regarding the total size of intended study populations, the precise data collected and the time periods in which the research activities should be completed.

Two main types of research activities can be distinguished:

a. ***A retrospective analysis of the 2014-15 outbreaks***, to "evaluate if the incidence of Legionellosis is associated with water quality" (Task 2.3.1; 2F).

This work has resulted in a manuscript (*Zahran et al.*). The MS concludes that the LD outbreaks of 2014-15 in GC were definitely due to the water regime change; arguments are based on statistical analyses comparing case incidences in census tracts in or outside Flint (including census tracts in the other counties) and in weeks before or during the water regime switch period in Flint, and some additional supporting analyses on relations with free chlorine concentrations.

The paper is difficult to follow in places and does not provide insight into the crude data with which the statistical analyses were performed. The authors claim that their analyses reveal causal relations, but failed to distinguish between the demonstration of a statistical association, and its interpretation as a causal relation.

The analysis of the water regime effect models the occurrence of legionellosis cases based on a series of variables. These include temperature, precipitation and humidity, percentage of population ≥ 50 years of age, and percent of households receiving public assistance. For the weather parameters it is not clear why they were selected/how they would be associated with indoor exposure to Legionella in residences. Outdoor temperature may be associated with the temperature of water in indoor plumbing systems (if not air-conditioned), but outdoor humidity and precipitation do not reflect humidity during showering. The method text does not formulate this correctly, humidity and precipitation have no "growth behavior effects", see Legionella literature on effects of humidity, heat and precipitation.

It is not clear to what extent the estimated effect of the water regime change on LD occurrence is affected by inclusion of these variables; would be useful to show unadjusted as well as adjusted results.

The random effects model cannot be reproduced, since the parameter values and constants are not incorporated. There is also no sensitivity analysis presented to show how sensitive the model outcome is to the different parameters.

The prediction of the free chlorine concentration in the drinking water in a neighbourhood and particularly in the residences of cases of legionellosis is based on measurements obtained at 8 monitoring locations only, and these measurements show high variability within and between stations, especially after the water regime change. Estimates of the free chlorine level in tap water in individual residences based on these measurements are likely to be very imprecise, and the validity of these estimates should be analysed, e.g. by looking at model performance against a hold-out proportion of the measurements themselves. This complexity may lead to significant differences between the free chlorine level that is predicted in the model used by the authors and the actual free chlorine level in the residences.

The hypothesis of water avoidance after the boil water advisory was issued is not substantiated. The boil water advisory was issued because of potential faecal contamination, for which ingestion is the exposure route of concern. The boil water advisory was directed towards drinking and other forms of ingestion, while the relevant exposure to Legionella is from aerosols in the shower, garden hosing or other water uses associated with aerosol droplet generation. There is no indication or substantiation that a boil water alert would lead to reduced exposure to aerosolized droplets from showering, garden hosing or use of the kitchen tap.

The temporal association with the switch back on October 16, 2015 and the lower number of LD cases in this period is used to suggest a causative relation between the two. But every increase in LD incidence subsided in the late fall/winter period, regardless whether they were in Genesee county in 2014 (when Flint was still on Flint river water) or in the other counties that were not on Flint water. This temporal association is therefore indicative, but not strong enough to claim that this "support the conclusion that the Flint LD outbreak was generally caused by water regime effects."

Some other critical issues:

- Categorization of cases as 'using Flint (river) water' in 2014-15 is based on the census tract of the residence; according to MDHHS information this is not precise – there would be substantial numbers of cases within Flint census tracts with anther water source, and some cases outside Flint who used Flint water.
- The reported high Odds Ratio's for cases in the 'interaction group' (post-switch period x Flint census tracts) are calculated with as reference groups census tracts outside Flint in Genesee county, and census tracts in Oakland and Wayne County, and in the pre-switch period. Wayne county however showed a large LD peak in 2013, thus in the pre-switch period, that probably strongly influenced the results, especially since Wayne county is considerably larger and the peak in 2013 thus represents absolute numbers that may be equal or larger than those of the LD outbreaks in Genesee county in 2014 and 2015. The authors have run models with in- and exclusion of the non-Flint census tracts in Genesee county, which had little impact, since GC is relatively small compared to the other counties. They should also have run models with exclusion of census tracts in Wayne county and/or Oakland county.
- The authors report an association between LD incidence in non-Flint census tracts and number of commuters into Flint from these tracts (Figure 6). Interestingly, although the highest number of commuters is very small compared to the numbers of inhabitants in the affected census tracts, the modelled LD incidence is rather larger in Figure 6 than it is in Figures 4 and 5 which are about LD incidence in the affected areas themselves. The maximum in Figure 6 is 0.015, in Figure 5 is is about 0.009, and in Figure 4 is is about 0.008. There is no explanation given. Also, there is no mention of the reservation that commuters into Flint are unlikely to be exposed to aerosolized water droplets – unless there would be sources in Flint such as cooling towers, but there is no mention of those.

We conclude that the final conclusions of the paper are not sufficiently supported by the analyses presented by the authors.

b. ***A prospective case-control study, with new cases in GC*** (Flint?) in 2016-17, and matched controls from Genesee county – either hospital based, or residential controls.

This part of the study is poorly described, and it is not clear what its primary objective should be: assessing risk factors for new LD outbreaks in GC, and/or assessment of the functioning of the surveillance and case reporting systems?

There is no statement regarding the numbers of cases and controls that the researchers expected to include. The table with power calculations (p. 28) suggests that there should be at least 40-50 cases and a few hundred controls. However, given the (fortunately) steep

decline of LD incidence since end 2015, the number of 40 cases will probably not be reached before the end of the project period.

It is not clear how controls would be recruited and motivated for participation, and which parameters matched with which cases.

No progress reports appear to be available; given above considerations it seems unlikely that a case-control population of sufficient size is now available for meaningful analyses.

In addition to the research activities, additional activities relating to public health and communication were mentioned in the FACHEP Phase II description:

*a) Activities to improve clinical awareness and rapid and adequate reporting of new cases, and evaluation of the existing surveillance system.*
***b)*** *Activities to improve knowledge about LD in the population; incorporated in outreach activities to local communities.*

There is no clear description of activities and the format of these results, and neither any reports of conducted work. There should be monthly internal reports and quarterly reports to MDHHS (page 29). No such reports have been available to the KWR team.

# Appendix VI Environmental microbiology

## Preliminary scientific assessment of FACHEP environmental studies

Comments and questions about the manuscript *Prevalence of infection competent Legionella pneumophila serogroup 6 within premise plumbing in Southeast Michigan*, by Brenda Byrne et al, corresponding author Michelle Swanson, University of Michigan.

### Review of manuscript

Overall: the key research outcomes are:

- that water/biofilm samples from premise plumbing in SE Michigan (both in Flint and in neighboring counties) contain *Legionella pneumophila* serogroup 6, sequence type 367 and 461, this is in line with findings in several other countries.

- that these environmental isolates show similar virulence (tested by ability to infect, survive and replicate in mouse macrophages) as clinical strains isolated in Michigan a virulent lab strain and two environmental isolates of *Legionella pneumophila* serogroup 1.

- that the urinary antigen test used to diagnose if *Legionella* is the cause of pneumonia is likely to underreport SG6, as the SG6 stains were not cross-reacting with the SG1 antigen used in this test.

The overall conclusion about the likely underreporting of SG6, as well as the statement about the importance of this, given that SG6 is the most common environmental isolate in this study and these isolates show similar virulence, is based on these findings and relevant for both the clinical and environmental microbiology of *Legionella* world-wide.

It is noteworthy that:

- 1 environmental isolate from a Flint shower is serogroup 1, sequence type 1, as are 4 clinical isolates. The discussion states that little genetic overlap between environmental and clinical strains was found.

- the incidence of residences that tested positive for Legionella in the culture test was similar in Flint and in non-Flint residences.

The wording of the manuscript about Legionella is accurate. The text in the introduction, as well as in the abstract (first sentence), the paragraph on Importance and the Discussion is suggestive towards a relation between the Legionella outbreak in Genesee County in 2014 and 2015 and the Flint water supply. Although it is valid to pose this as hypothesis, this is not studied here, since the environmental isolates are collected in 2016 and the origin of the clinical isolates is not clear (Flint area residents, other regions?). In relation to this comment, it is noted that the paper lacks a clear study objective, but points to the FACHEP team and strategy instead, which further adds to the suggestion.

The description of the cause of lead in Flint tap water in the introduction is too simple (the cause was more complex than just omitting orthophosphate dosing).

The results section, methods section and legend to fig 1 show a discrepancy in the number of residences sampled (130 vs 187 enrolled/130 sampled vs 188).

The number of samples from control residences was too low to allow testing for significant differences with Flint. The manuscript does not mention how many residences from Flint and outside Flint were sampled. Fig 1 shows 10 residences positive in Flint, the text shows 17 residences positive in Genesee county and 2 residences (isolates) from Detroit. If 10 residences in Flint is equivalent to 12%, this would mean a total of 81-86 residences in Flint have been sampled. With a total of 130 residences in the study, this would mean 44-49 residences outside of the Flint area. With 7 positive residences outside of the Flint area this would mean 18-20% of the residences are positive.

The study would have benefited from inclusion of isolates from water mains inside and outside the City of Flint, as this would give further information on the occurrence and types of *L. pneumophila* strains in the water distribution system outside premise plumbing.

The clinical isolates are from 2013-2016, that hospitals in Genesee, Wayne and Oakland counties submitted to the MDHHS lab. There is no information about the residency of the cases that 'produced" these isolates, so no geographical link can be made between clinical isolates and Flint water, or any other source of exposure.

There is an overrepresentation (16/18) of Flint environmental isolates used in the typing and virulence study.

Method section: limited to no description of QA for the methods used.

Discussion: results are placed within appropriate context of international studies and are in line. The sentence about the average number of deaths due to pneumonia is using a non-scientific reference.

In the printed version of the manuscript the word(s) *Legionella* or *Legionella pneumophila* are sometimes missing (for example in the title and first sentence of the introduction). This has not hampered the review.