ULSTER COUNTY BOARD OF HEALTH

September 21, 2015

AGENDA

CALL TO ORDER

- **OLD BUSINESS**
  a. Approval of the August 2015 minutes

- **NEW BUSINESS**

  a. Commissioner's Report:
     - SUNY Ulster AED
     - Cooling Towers
     - Vaccinations in Schools
     - Streptococcus Pneumoniae Case
     - Opioid Issue – UCAN Recommendations

  b. Patient Services Report
     - Influenza Vaccination Fee 2015-2016 Season
     - Employee Flu Vaccination Program
     - Ulster County ServNY Volunteer Management Program
     - MMWR Q-fever Outbreak
     - Performance Incentive: STD Standard

MEETING CONCLUSION

Ulster County Board of Health

Golden Hill Office Building
239 Golden Hill Lane
Kingston, NY 12401

Date: Monday, September 21, 2015

Board Members		Signature
Cardinale RN GCNS-BC, Anne	Board Member	
Delma MD, Dominique	Secretary	Excused
Graham ESQ, Peter	Board Member	
Hildebrandt MPA, Mary Ann	Member	Excused
Kelly RN, Elizabeth	Board Member	
Tack DO, Marc	Chairman	
Woodley MD, Walter	Vice Chairman	

Department of Health and Mental Health		Signature
Smith, MD, MPH, Carol	Commissioner of Health and Mental Health	
Heller MD, Douglas	Medical Examiner	Excused
Veytia RN, MSN, Nereida	Deputy and Director of Patient Services	
Mertens PE, Shelley	Director of Environmental Health Services	Excused
McCracken, Amy	UC Depart of MH Deputy Commissioner	Excused

Guests		Signature

Ulster County Board of Health
September 21, 2015

Members PRESENT: Anne Cardinale, RN GCNS-BC, Board Member
Peter Graham, ESQ, Board Member
Marc Tack, DO, Chairman
Elizabeth Kelly, RN, Board Member

DOH/DMH PRESENT: Carol Smith, MD, MPH, Commissioner of Health
Nereida Veytia, Deputy/Patient Services Director

GUESTS: None

ABSENT: Walter Woodley, MD, Board Member

EXCUSED: Mary Ann Hildebrandt, MPA, Board Member
Dominique Delma, MD, Secretary
Douglas Heller, MD, Medical Examiner
Shelley Mertens, Environmental Health Director
Amy McCracken, Deputy Commissioner of MH

I. **Approval of Minutes:** A motion to approve of the August 2015 minutes was made by Mr. Graham, seconded by Ms. Kelly and unanimously approved.

II. **Agency Reports:**

a. Commissioner's Report: Dr. Smith reported on the following:

- **SUNY Ulster:** The County Executive recognized SUNY Ulster as being a Heart Safe site. This took place on September 15th at the new SUNY Ulster Kingston site. This site which was formerly an elementary school was converted into the college's satellite site through the STRIVE program. The project was paid for through grants and no taxpayer dollars were used. The building and grounds is environmentally friendly which includes water drainage systems, watering gardens, and efficiency lighting. This will replace the satellite site at the Ulster County Business Resource Center. The County Executive said the new location will open more accessibility to the college for the students at the Kingston High School. Dr. Smith would like to schedule a future Board meeting at the site for the Board to see the new location.
- **Cooling Towers:** Due to the recent Legionnaires outbreak in the Bronx which was caused by the mist from cooling towers, NYS Department of Health has informed local health departments of the new registry system for facilities with such towers. The database requires these facilities to register their towers and will also record proof of inspections and proof of water sampling results. There has been much discussion regarding identifying these towers and the oversight of such facilities. The role of the local health department is vague. Still awaiting more guidance from the State.

- **Vaccinations in Schools:** The NYS Department of Health Letter and newly amended guidelines for school immunization requirements was distributed and reviewed (see attached).
- **Streptococcus Pneumoniae Case:** Dr. Smith discussed with the Board a reported bacterial (streptococcus pneumoniae) meningitis case the Communicable Disease Division was involved with the investigation of.
- **Opioid Issue - UCAN Recommendations:** The Ulster Coalition Against Narcotics (UCAN) submitted to the Commissioner a list of recommendations they thought were needed to be established in order to address the opioid issue. A response to the recommendations was made. Dr. Smith will bring the recommendations and response to the next meeting.

b. Medical Examiner's Report: No Report

c. Patient Services Report:

- **Influenza Vaccination Fee 2015-2016 Season:** The cost analyst to administer flu vaccines was submitted to the Board for review and approval (see attached). A motion was made to accept the fees by Mr. Graham, seconded by Dr. Tack and unanimously approved.
- **UC ServNY Volunteer Management Program:** The Preparedness deliverable for 2015-2016 to test the deploying of volunteers to assist instances of emergencies such as a bio terrorist attack. UCDOH is currently reaching out to various groups to populate a database of individuals willing to volunteer should the need arise. The ServNY request for volunteer flyer was distributed to the Board (see attached).
- **MMWR Q-fever Outbreak:** The Ulster County DOH Communicable Disease Division was recognized by the Morbidity and Mortality Weekly Report (MMWR) for their role and response to a Q-fever outbreak which involved six (6) individuals of who three (3) were Ulster County residents (see attached).
- **Performance Incentive: STD Standard:** The New York State Department of Health has awarded the Ulster County Department of Health's Patient Services Division $20,900 in a competitive performance grant. The 2014-2015 Local Health Department Performance Incentive Initiative focused on sexually transmitted disease and general communicable disease control reporting measures. NYSDOH measured timely investigations and reporting over a six (6) month period of time. The NCDOH Nursing Division produced a total composite score across all measures of 99.3% during the performance period for this competitive award.

Meeting Adjournment: A motion was made by Mr. Graham to adjourn the meeting, motion was seconded by Ms. Cardinale and unanimously approved.

Next Meeting: The next meeting is scheduled for October 5, 2015.

Respectfully submitted by:

Katrina Kouhout

Katrina Kouhout
Secretary to the Commissioner of Health and Mental Health
On behalf of UC Board of Health

NEW YORK STATE OF OPPORTUNITY. | Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

August 26, 2015

Dear Colleague:

The purpose of this letter is to inform you about recently adopted amendments to regulations at 10 NYCRR Subpart 66-1 addressing school immunization requirements. The amendments take effect on September 1, 2015. It is important that health care providers understand the changes to the immunization requirements because schools are required under Public Health Law § 2164 to exclude students from school who have not met the immunization requirements for school entrance and attendance. Parents look to their health care providers for information regarding immunizations, so it is important for providers to know the school immunization requirements.

Effective September 1, 2015, students entering school will be required to have completed all required vaccine series upon school entry. The only exceptions to this requirement are children with acceptable evidence of immunity, valid medical or religious exemptions to vaccination, or in the process of completing vaccinations according to the Advisory Committee on Immunization Practices (ACIP) schedule. Doses of vaccines recommended for administration at four to six years of age, e.g., measles, mumps and rubella (MMR); diphtheria and tetanus toxoids and acellular pertussis (DTaP); and poliovirus vaccines, are now required to be received prior to school entry.

A chart describing the vaccines required for each grade is attached. *Please note* that children who received doses of vaccine before the minimum age or intervals specified by the ACIP schedule will be required to repeat the invalid dose or show other evidence of immunity in order to continue to attend school.

In addition, children will need to receive at least five doses of DTaP vaccine, or at least four doses, if the final dose was received at four years of age or older. Children seven years of age or older who did not receive a complete DTaP series will be required to complete the series prior to school entry this year with a dose of pertussis containing vaccine (i.e. Tdap), followed by tetanus and diphtheria toxoids (Td) if additional doses are needed. This is in accordance with ACIP and American Academy of Pediatrics recommendations and is the standard of care in the United States. A dose of Td vaccine given in place of the required Tdap vaccine will not meet the requirements to attend school unless the child has a medical exemption to receipt of pertussis-containing vaccine. A dose of Tdap vaccine received on or after seven years of age will also satisfy the sixth grade Tdap vaccine requirement. Cases and outbreaks of pertussis have increased nationwide over the last ten years; for this reason, it is of critical importance to ensure that all children are fully protected against pertussis in order to attend school.

Finally, all schools in New York State have access to either the New York State Immunization Information System (NYSIIS) and/or the Citywide Immunization Registry (CIR). It is important for health care providers to keep patient immunization records up to date in NYSIIS and the CIR as schools will be using NYSIIS and the CIR to determine whether the vaccine doses required for school entrance and attendance were received at the appropriate ages and intervals. If information is not found in NYSIIS or the CIR, then your office will need to provide signed paper vaccine records.

If you have any questions regarding these changes to the regulations, please contact the New York State Department of Health Bureau of Immunization at one of the following telephone numbers:

Central Office - Albany	(518) 474 – 1944
Capital District	(518) 473 – 4437
Western Regional Office	(716) 847 – 4501
Rochester Field Office	(585) 423 – 8097
Syracuse Regional Office	(315) 477 – 8164
New Rochelle Field Office	(914) 654 – 7149
Central Islip Office	(631) 851 – 3096
Monticello District Office	(845) 794 – 5627

In New York City, please contact the New York City Department of Health and Mental Hygiene's Bureau of Immunization at (347) 396 – 2433.

Thank you for your assistance in ensuring that all children in New York State are appropriately immunized.

Sincerely,

Elizabeth Rausch-Phung, M.D., M.P.H.
Director, Bureau of Immunization

2015-16 School Year

New York State Immunization Requirements for School Entrance/Attendance[1]

NOTES: Children in a prekindergarten setting should be age-appropriately immunized. The number of doses depends on the schedule recommended by the Advisory Committee for Immunization Practices (ACIP).

For grades Pre-k through 7, intervals between doses of vaccine should be in accordance with the ACIP-recommended immunization schedule for persons 0 through 18 years of age. (Exception: intervals between doses of polio vaccine need to be reviewed only for grades kindergarten, 1, 6 and 7.) Doses received before the minimum age or intervals are not valid and do not count toward the number of doses listed below. Intervals between doses of vaccine DO NOT need to be reviewed for grades 8 through 12. See footnotes for specific information for **each** vaccine. Children who are enrolling in grade-less classes should meet the immunization requirements of the grades for which they are age equivalent.

Dose requirements MUST be read with the footnotes of this schedule.

Vaccines	Prekindergarten (Day Care, Head Start, Nursery or Pre-k)	Kindergarten through Grade 1	Grades 2 through 5	Grades 6 through 7	Grades 8 through 12
Diphtheria and Tetanus toxoid-containing vaccine and Pertussis vaccine (DTaP/DTP/Tdap)[2]	**4 doses**	**5 doses or 4 doses** if the 4th dose was received at 4 years of age or older or **3 doses** if the series is started at 7 years of age or older		**3 doses**	
Tetanus and Diphtheria toxoid-containing vaccine and Pertussis vaccine booster (Tdap)[3]		Not applicable		**1 dose**	
Polio vaccine (IPV/OPV)[4]	**3 doses**	**4 doses or 3 doses** if the 3rd dose was received at 4 years of age or older	**3 doses**	**4 doses or 3 doses** if the 3rd dose was received at 4 years of age or older	**3 doses**
Measles, Mumps and Rubella vaccine (MMR)[5]	**1 dose**	**2 doses**			
Hepatitis B vaccine[6]	**3 doses**	**3 doses** or **2 doses of adult hepatitis B vaccine** (Recombivax) for children who received the doses at least 4 months apart between the ages of 11 through 15 years of age			
Varicella (Chickenpox) vaccine[7]	**1 dose**	**2 doses**	**1 dose**	**2 doses**	**1 dose**
Haemophilus influenzae type b conjugate vaccine (Hib)[8]	**1 to 4 doses**	Not applicable			
Pneumococcal Conjugate vaccine (PCV)[9]	**1 to 4 doses**	Not applicable			

1. Demonstrated serologic evidence of measles, mumps, rubella, hepatitis B, varicella or polio (for all three serotypes) antibodies is acceptable proof of immunity to these diseases. Diagnosis by a physician, physician assistant or nurse practitioner that a child has had varicella disease is acceptable proof of immunity to varicella.

2. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)
   a. Children starting the series on time should receive a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15 through 18 months, and 4 years of age or older. The fourth dose may be received as early as age 12 months, provided at least 6 months have elapsed since the third dose. However, the fourth dose of DTaP need not be repeated if it was administered at least 4 months after the third dose of DTaP. The final dose in the series must be received on or after the fourth birthday and at least 6 months after the previous dose.
   b. If the fourth dose of DTaP was administered at age 4 years or older, the fifth (booster) dose of DTaP vaccine is not necessary.
   c. For children born prior to 1/1/2005, doses of DT and Td meet the immunization requirement for diphtheria toxoid-containing vaccine.
   d. Children ages 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. A Tdap vaccine (or incorrectly administered DTaP vaccine) received at 7 years or age or older will meet the 6th grade Tdap requirement.
   e. For previously unvaccinated children 7 years of age and older, the immunization requirement is 3 doses. Tdap should be given for the first dose, followed by two doses of Td in accordance with the ACIP recommended immunization schedule for persons 0-18 years of age: an initial Tdap followed 4 weeks later by a Td, and 6 months later by another Td.

3. Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 7 years)
   a. Students 11 years of age or older entering grades 6 through 12 are required to have one dose of Tdap. A dose received at 7 years of age or older will meet this requirement.
   b. Students who are 10 years old in grade 6 are in compliance until they turn 11 years of age.

4. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)
   a. Children starting the series on time should receive a series of IPV at ages 2, 4, 6 through 18 months, and 4 years of age or older. The final dose in the series should be received on or after the fourth birthday and at least 6 months after the previous dose.
   b. For students who received their fourth dose before August 7, 2010, 4 doses separated by at least 4 weeks is sufficient.
   c. If the third dose of polio vaccine was received at age 4 years or older, the fourth dose of polio vaccine is not necessary.

5. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months)
   a. The first dose of MMR vaccine must have been received on or after the first birthday. The second dose must have been received at least 28 days (4 weeks) after the first dose to be considered valid.
   b. Students in grades kindergarten through 12 must have received 2 doses of measles-containing vaccine, 2 doses of mumps-containing vaccine and at least 1 dose of rubella-containing vaccine.
   c. One dose of MMR is required for prekindergarten.

6. Hepatitis B vaccine
   a. Dose 1 may be given at birth or anytime thereafter. Dose 2 must be received at least 4 weeks (28 days) after dose 1. Dose 3 must be at least 8 weeks after dose 2 AND at least 16 weeks after dose 1 AND no earlier than 24 weeks of age.
   b. Two doses of adult hepatitis B vaccine (Recombivax) received at least 4 months apart at age 11 through 15 years will meet the requirement.

7. Varicella (chickenpox) vaccine. (Minimum age: 12 months)
   a. The first dose of varicella vaccine must have been received on or after the first birthday. The second dose must have been received at least 28 days (4 weeks) after the first dose to be considered valid.
   b. Two doses of varicella vaccine are required for students in grades kindergarten, 1, 6 and 7.
   c. One dose of varicella vaccine is required for prekindergarten and grades 2 through 5 and 8 through 12.

8. Haemophilus influenzae type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)
   a. Children starting the series on time should receive Hib vaccine at 2 months, 4 months, 6 months and 12 through 59 months of age.
   b. If 2 doses of vaccine were received before 12 months of age, only 3 doses are required with dose 3 at 12 through 15 months of age and at least 8 weeks after dose 2.
   c. If dose 1 was received at ages 12 through 14 months of age, only 2 doses are required with dose 2 at least 8 weeks after dose 1.
   d. If dose 1 was received at 15 months of age or older, only 1 dose is required.
   e. Hib vaccine is not required for children 5 years of age or older.

9. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)
   a. Children starting the series on time should receive PCV vaccine at ages 2 months, 4 months, 6 months and 12 through 59 months of age. The final dose must be received at 12 through 59 months of age.
   b. Unvaccinated children 7 through 11 months of age are required to receive 2 doses, at least 4 weeks apart, followed by a third dose at age 12 through 15 months.
   c. Unvaccinated children 12 through 23 months of age are required to receive 2 doses of vaccine at least 8 weeks apart.
   d. If one dose of vaccine was received at 24 months of age or older, no further doses are required.
   e. For further information, refer to the PCV chart available in the School Survey Instruction Booklet at: www.health.ny.gov/prevention/immunization/schools

For further information contact:

New York State Department of Health
Bureau of Immunization
Room 649, Corning Tower ESP
Albany, NY 12237
(518) 473-4437

New York City Department of Health and Mental Hygiene
Program Support Unit, Bureau of Immunization,
42-09 28th Street, 5th floor
Long Island City, NY 11101
(347) 396-2433

2015 Flu Cost & Recommended Charges for September BOH Meeting
Robin Nigro to: Nereida Veytia 09/09/2015 08:30 AM
Cc: Carol Smith, Kristin Carney, Katrina A Kouhout

Boudy

As requested, the following is the estimated cost to administer flu vaccines at the 2015 clinics. Staff cost includes Nurses, Clerical Support, & Billing Clerk; Supply cost includes direct patient supplies. Vaccine cost is at the current cost. Overhead is not calculated in; therefore, the recommendation is $20/vaccine.

Cost Per Dose	Flu
2012 Count:	249
2013 Count:	230
2014 Count:	156
Admin Cost (Est)	
Nursing PS/FB	$ 6.34
Clerical PS/FB	$ 2.26
Tot PS/FB	**$ 8.60**
Vaccine Cost	**$ 9.67**
Supply	**$ 0.63**
Recommendation	**$ 20.00**
Charges Adopted by BOH	

Note: 2014 Charge = $20.

If you have any questions, please feel free to contact me.

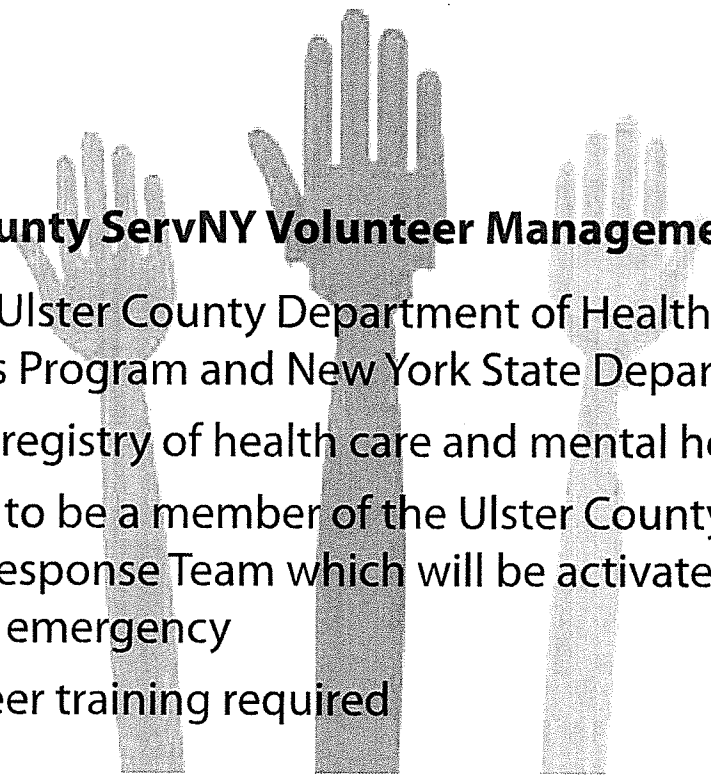
Thanx,
Robin F (Nigro) Bissinger
Fiscal Manager

Ulster County Department of Health
Golden Hill Office Building
239 Golden Hill Lane
Kingston, NY 12401-6441
(845) 340-3158 or Internal x3158
(845) 340-4150 Fax
E-Mail: rnig@co.ulster.ny.us

WANTED:

Licensed Health and Mental Health Care Professionals to Volunteer

FOR A SPECIAL MISSION



The Ulster County ServNY Volunteer Management Program is:

- Managed by Ulster County Department of Health-Public Health Preparedness Program and New York State Department of Health
- A web based registry of health care and mental health professionals
- Register now to be a member of the Ulster County ServNY Emergency Response Team which will be activated during a local public health emergency
- Some volunteer training required

For questions, please call:

Ann Smoller, Preparedness Coordinator: **845-334-5540**

Diane Aznoe, Preparedness Educator: **845-334-5538**

Register Online at:

https://apps.health.ny.gov/vms/appmanager/vms/public?prog=53

Ulster County of Department of Health

Michael P. Hein, County Executive

Carol Smith, MD, MPH, Commissioner

Q Fever Outbreak among Travelers to Germany Associated with Live Cell Therapy — United States and Canada, 2014

Misha P. Robyn, DVM[1,2], Alexandra P. Newman, DVM[2], Michael Amato, MPH[3], Mary Walawander[3], Cynthia Kothe[4], James D. Nerone[4], Cynthia Pomerantz[4], Casey Barton Behravesh, DVM[5], Holly M. Biggs, MD[1,5], F. Scott Dahlgren[5], Emily G. Pieracci, DVM[1,5], Yvonne Whitfield, MPH[6], Doug Sider, MD[6], Omar Ozaldin, MSc[7]; Lisa Berger, MD[7]; Peter A. Buck, DVM[8], Mark Downing, MD[9,10], Debra Blog, MD[2] (Author affiliations at end of text)

During September–November 2014, the New York State Department of Health (NYSDOH) was notified of five New York State residents who had tested seropositive for *Coxiella burnetii*, the causative agent of Q fever. All five patients had symptoms compatible with Q fever (e.g., fever, fatigue, chills, and headache) and a history of travel to Germany for live cell therapy during May 2014. Live cell therapy, also known as fresh cell treatment, is the practice of injecting processed cells from organs, embryos, or fetuses of nonhuman animals (e.g., sheep) into human recipients *(1)*. It is advertised to treat a variety of health conditions. This practice is unavailable in the United States; however, persons can travel to foreign locations to receive injections. Local health departments (LHDs) interviewed the patients and NYSDOH notified CDC and posted a report on CDC's Epidemic Information Exchange to identify additional cases. Clinical and exposure information for each patient was reported to the Robert Koch Institute in Germany. Clinicians should be aware of health risks from live cell therapy, and consider Q fever and other zoonotic diseases among patients with a history of receiving fresh cell injections.

The five patients had traveled in a group of 10-15 persons to the German Rhineland-Palatinate state to receive intramuscular injections of fetal sheep cells by a German physician on May 30,

2014. One patient reported hearing about the trip from a friend, and that these trips were organized on a twice yearly basis. The other group members and trip organizer are unknown. A Canadian resident, who also received live cell therapy on May 28, 2014, was a Q fever diagnosis in July 2014. Under the International Health Regulations, the Public Health Agency of Canada notified German authorities in September 2014. At the time of notification, the Robert Koch Institute, part of the German Federal Ministry of Health, was investigating an outbreak of human Q fever associated with inhalation exposure to a sheep flock that was used for production of live cells by the German physician.

In September, the German physician notified patients treated during January–July 2014 of their potential Q fever exposure. This prompted Q fever testing of the five patients in New York, three of whom had already sought medical care for symptoms. The remaining two patients had experienced symptoms but had not sought medical care until notification of their potential Q fever exposure. The positive titers were reported to NYSDOH after laboratory diagnosis and prompted investigation by LHD. No residents from other U.S. states with positive Q fever titers and history of live cell therapy in Germany have been identified. It is unknown if the remaining patients did not get tested for Q fever, tested negative, or did not report a live cell therapy exposure.

A case was defined as a person who received live cell therapy in Germany during May 2014, experienced clinical signs and symptoms compatible with Q fever, and had a single IgG titer ≥1:128 to *C. burnetii* phase II antigen by immunofluorescence assay *(2)*. The median patient age was 61 years (range: 59–83 years). Three (60%) of the five patients were female. None of the patients reported other potential exposures for Q fever, with the exception of one patient reporting contact with sheep horn or bone. Two patients reported preexisting medical conditions;

one patient reported atrial fibrillation and kidney stones, and one patient reported Parkinson's disease and osteoarthritis.

Signs and symptoms began within approximately one week of exposure. The majority of symptoms were reported as lasting approximately 10–90 days; however, 9–10 months after exposure, three patients continued to report symptoms of fatigue, chills, sweats, and difficulty sleeping (Table). One patient had initially denied symptoms during an interview with LHD after his positive titers were reported in November 2014, but in February 2015 reported to his physician that symptoms had been occurring since the injections in May.

The patients were tested for Q fever phase I and phase II antigens at 4–6 months after exposure. All patients' IgG phase I titers were elevated (1:512–1:2048), but were less than IgG phase II titers (1:4096–1:65,536), providing evidence of acute disease. IgM phase I titers were elevated in three patients (1:128–1:8192) and IgM phase II titers were elevated in all patients (1:64–1:32,768). All patients were treated with doxycycline after the Q fever diagnosis was made.

All five patients were initially interviewed by LHDs, but only two patients agreed to a second follow-up interview by NYSDOH. These two patients reported that a group traveled to Germany for injections on a twice yearly basis for the past five years. They chose to receive live cell therapy to improve general health and vitality, and had not previously experienced signs or symptoms of illness after injections. They reported that they were not informed of a risk for Q fever infection before injection.

Discussion

Live cell therapy was developed in Switzerland during the 1930s by Paul Niehans. Practitioners can use organs, glands, and embryos of multiple species, including sheep, cows, and sharks* *(1)*. In 1984, the U.S. Food and Drug Administration (FDA) banned importation of cellular products

intended for injection *(3)*, however the practice continues outside the United States, notably in Germany.

No published clinical evidence supporting therapeutic claims of live cell therapy is available. It is advertised as having antiaging effects and as a treatment for multiple diseases (e.g., erectile dysfunction, depression, and joint, neurologic, heart, kidney, lung, endocrine, and liver disease).† Serious adverse events have been reported, including anaphylaxis, vasculitis, encephalitis, polyradiculitis, clostridial infections, paresis, and death *(4–6)*.

Live cell therapy is a type of xenotransplantation because it involves infusion of live cells from a nonhuman animal source into a human recipient *(7)*. Xenotransplantation carries a public health risk for transmission of known and unknown infectious agents from the donor organism to the human recipient and possible recombination or reassortment to form new pathogens *(7)*. There is a theoretic potential for dissemination of disease from the original recipient to others. For this reason, discussions on safety requirements for xenotransplantation by international and domestic public health agencies continue to occur *(8)*. Regulation of xenotransplantation varies across countries. In the United States, FDA regulates xenotransplantation products under section 351 of the Public Health Service Act [42 U.S.C. 262] and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321 et seq]. In Canada, xenotransplantation cell therapy products are regulated as drugs under the Food and Drugs Act [R.S.C., 1985, c. F-27] and the Food and Drug Regulations [C.R.C., c. 870]. Authorities in Canada have not authorized for sale any xenotransplantation products, nor have any clinical trials been authorized that involve xenotransplantation. In Germany, xenotransplantation products are regulated under the Medicinal Products Act *(ARZNEIMITTELGESETZ-AMG)*; however, an attempt to ban fresh cell therapy in 1997 was later determined to be null and void as the law does not cover drugs manufactured by doctors for

use in their patients *(9)*. According to an assessment supported by the World Health Organization and its partners, during January 1994–September 2009, xenotransplantation procedures were identified in 12 different countries, 9 with no clear national regulations on xenotransplantation *(10)*.

This outbreak highlights one of the public health issues associated with xenotourism. FDA recommends that xenotransplantation product recipients enrolled in research studies remain under life-long surveillance with periodic clinical and laboratory monitoring and that both they and their intimate contacts refrain from blood and tissue donation *(7)*, but other than self-reporting, no method to identify returned xenotourists is available. Clinicians should be aware of xenotourism and consider zoonotic disease potential in a patient with a history of xenotransplantation.

Acknowledgments

Stephen Moore, Ryan Walton, Bryna Warshawsky, MD, Public Health Ontario. Ann Sullivan-Frohm, Christina Hidalgo, MPH, Philip Kurpiel, PhD, New York State Department of Health. Canada IHR National Focal Point Office, Public Health Agency of Canada.

[1]Epidemic Intelligence Service, Division of Scientific Education and Professional Development, CDC; [2]New York State Department of Health; [3]Erie County Department of Health; [4]Ulster County Department of Health and Mental Health; [5]Division of Vector-Borne Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC; [6]Public Health Ontario Agency for Health Protection and Promotion; [7]Toronto Public Health; [8]Centre for Food-borne,

Environmental and Zoonotic Infectious Diseases, Public Health Agency of Canada; [9]Saint Joseph's Health Centre, Toronto, Ontario; [10]Department of Medicine, University of Toronto

* http://www.extendlife.com/livecell.php.

† http://www.janson-mueller.de/index.php?id=22&L=2.

References

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4. Bohl J, Goebel HH, Potsch L, Esinger W, Walther G, Mattern R, et al. Complications following cell therapy. Zeitschrift fur Rechtsmedizin 1989;103:1–20.
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Summary

What is already known on this topic?

Q fever is a zoonotic disease caused by *Coxiella burnetii* and is usually transmitted through inhalation of air contaminated with animal excreta. It is considered to be underdiagnosed because symptoms are non-specific and can vary from patient to patient, making diagnosis difficult.

What is added by this report?

During September–October 2014, New York State Department of Health identified five Q fever cases with exposure to live cell therapy, an alternative medicine practice involving injections of fetal sheep cells, which is a type of xenotransplantation. Investigation revealed that a group of U.S. citizens travel to Germany on a twice yearly basis to receive this treatment.

What are the implications for public health practice?

Clinicians should consider zoonotic diseases, like Q fever, in patients with a history of live cell therapy. International travel for xenotransplantation procedures can allow for zoonotic transmission of disease.

TABLE. Signs and symptoms reported by live cell therapy-exposed Q fever patients

Symptom	Patient 1	Patient 2*	Patient 3	Patient 4	Patient 5
Fever	X		X	X	X
Sweats	X		X	X	X
Fatigue	X	X		X	X
Headache	X		X		X
Chills	X	X	X		
Malaise			X	X	X
Cellulitis			X		X
Confusion	X				
Retrobulbar pain	X				
Injection site abscess			X		
Cough			X		
Dizziness			X		
Shortness of breath			X		
Sore throat			X		
Dry mouth			X		
Diarrhea			X		
Difficulty sleeping				X	
Joint pain					X
Myalgia					X
Duration	10–30 days	9 months (fatigue and chills ongoing as of February 2015)	2–3 months	14–30 days (fatigue and difficulty sleeping ongoing as of February 2015)	30 days (fatigue and sweats ongoing as of February 2015)

*Patient 2 initially denied symptoms.